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Practice and outcomes for radical urological cancer surgery in England: a study based on Hospital Episode Statistics and a review of the literature

Mr Martin Nuttall MA MBBS MRCS

Clinical Effectiveness Unit

The Royal College of Surgeons of England

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Abstract

Complete, timely and accurate data are needed to monitor the quality of surgical care in the UK. However, large-scale national audits are labour-intensive and expensive. Furthermore, within surgery many studies have noted wide variation between post-operative outcomes amongst hospitals. Studies have also tried to determine whether the number of cases performed at a hospital is one component that can influence surgical outcomes. With this in mind, the overall aims of this thesis were to describe the practice and outcomes for radical urological cancer surgery in England, and to determine whether the number (or 'volume') of procedures that a hospital carries out is a potential determinant of outcomes.

The objectives of this thesis were fivefold. Firstly, to use administrative data from Hospital Episode Statistics (HES) of the English Department of Health between 1995 and 2002 to report activity and outcomes for patients recorded as having undergone a radical prostatectomy (RP), radical cystectomy (RC) or radical nephrectomy (RN).

Secondly, to develop and validate a comorbidity index for the first time within the HES database. The obtained index, based on the Charlson score, increased with age, was higher in patients admitted as an emergency, and also predicted outcomes.

Thirdly, to review the literature to establish to what extent volume could be an explanation for variation in outcomes between surgical providers. This review concluded that surgical outcomes, on average, should improve with increasing hospital or surgeon volume, although the evidence for RN was weakest.

Fourthly, to establish, through conducting a national survey, the views of the surgeons performing these procedures regarding 'volume and outcome' relationships. This survey discovered that most consultants supported the principle of volume thresholds, but with wide variation as to where thresholds should be set.

Finally, to determine through analysis of the HES data whether post-operative outcomes in England depend on the volume of procedures that a hospital performs. In brief, hospital volume was inversely related to in-hospital mortality following RC. No similar effect was demonstrable following RN. No effect of volume on length of stay after RC or RN was identified, but length of stay after RP was shorter in high volume hospitals. Data from this thesis provides some evidence in support of volume-based health policies for RC, but less support for such policies relating to RN or RP.

Journal publications arising from this research

Charlson scores based on ICD-10 administrative data are valid to assess comorbidity in patients undergoing radical urological cancer surgery
Martin Nuttall, Jan van der Meulen, Mark Emberton
Journal of Clinical Epidemiology 2006; 59(3):265-273

From the many to the few: changes in urological cancer surgery provision
Martin Nuttall, Jan van der Meulen, Mark Emberton
British Journal of Cancer 2005; 92:797-798

Description of Radical Nephrectomy Practice and Outcomes in England: 1995–2002
Martin Nuttall, Paul Cathcart, Jan van der Meulen, David Gillatt, Gregor McIntosh, Mark Emberton
British Journal of Urology International 2005; 96:58-61

A systematic review and critique of the literature relating volume to outcome for three urological cancer procedures
Martin Nuttall, Jan van der Meulen, Nirree Phillips, Carlos Sharpin, David Gillatt, Gregor McIntosh, Mark Emberton
Journal of Urology 2004; 172(6):2145-2152

Threshold volumes for urological cancer care: survey of UK urologists
Martin Nuttall, Jan van der Meulen, Gregor McIntosh, David Gillatt, Mark Emberton
British Journal of Urology International 2004; 94:1010-1013

The relationship between volume and outcome in urological surgery

Martin Nuttall, Mark Emberton, Jan van der Meulen

British Journal of Urology International 2004; 94:677-678

Temporal changes in patient characteristics and outcomes for radical cystectomy in England.

MC Nuttall, J van der Meulen, G McIntosh, D Gillatt, M Emberton

British Journal of Urology International 2005; 95:513-516

Presentations to learned societies arising from this research

Radical Nephrectomy Practice in England 1995-2002

European Association of Urology Annual Congress, Istanbul, Turkey, 2005

Validity of Charlson comorbidity scores based on ICD-10 administrative data to assess comorbidity in patients undergoing radical urological cancer surgery in England.

American Urological Association Annual Meeting, San Antonio, Texas, USA, 2005

Radical Nephrectomy practice in England 1995-2002.

British Association of Urological Surgeons Annual Conference, Glasgow, UK, 2005

A systematic review of the literature relating hospital and surgeon volume to outcome for three urological cancer procedures.

British Association of Urological Surgeons Annual Conference, Harrogate, UK, 2004

Urological Cancer Care: survey of UK provider volumes and volume threshold levels.

British Association of Urological Surgeons Annual Conference, Harrogate, UK, 2004

Temporal trends in radical cystectomy: UK Hospital Episode Statistics data 1995-2001.

European Association of Urology Annual Conference, Vienna, Austria, 2004

UK hospital and surgeon volumes for urological cancer care and surgeons' views on minimum volume thresholds

European Association of Urology Annual Conference, Vienna, Austria, 2004

Temporal trends in radical prostatectomy: UK Hospital Episode Statistics data 1995-2001

American Urological Association Annual Conference, San Francisco, USA, 2004

Temporal trends in radical cystectomy: UK Hospital Episode Statistics data 1995-2001

American Urological Association Annual Conference, San Francisco, USA, 2004

Surgeons' views on volume thresholds for urological cancer care

World Congress of Urological Research, London, UK, 2004

Radical prostatectomy: who should perform it and where? Surgeons' views

British Prostate Group, Edinburgh, UK, 2003

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Martin Nuttall, August 2005.

Statement of originality and involvement

This work has not previously been accepted in any substance for any degree and is not concurrently submitted in candidature for any degree.

This thesis is the result of my own investigations, except where otherwise stated. Other sources are acknowledged by explicit references. A bibliography is appended.

I hereby give consent for my thesis, if accepted, to be available for photocopying and inter-library loan, and for the title and abstract to be made available to outside organisations.

Signed .... (Candidate)

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Section 1

Introduction and General Overview

Chapter 1

Introduction

1.1 Introduction and objectives of thesis

This thesis describes work I undertook during a 26-month period as a research fellow attached to the Clinical Effectiveness Unit at the Royal College of Surgeons of England. The thesis is divided into five sections, each sub-divided into chapters describing differing aspects of this work.

The objectives of this thesis were fivefold. Firstly, to use administrative data from the Hospital Episode Statistics (HES) database of the Department of Health in England to report surgical activity and outcomes for radical urological cancer surgery. Secondly, to develop and to validate a comorbidity score that adjusts for casemix within the HES database. Thirdly, to systematically review the literature to establish to what extent variation in volume could be an explanation for variation in outcomes between hospitals. Fourthly, to establish, through conducting a national survey, the views of the surgeons performing these procedures regarding 'volume and outcome' relationships. Finally, to determine through analysis of the HES data whether post-operative outcomes following radical urological cancer surgery in England depend on the volume of procedures that a hospital performes.

Section one is a general introduction to the thesis and this section also contains a summary of the treatment options for localised carcinoma of the prostate, bladder and kidney for non-urological readers of this thesis. The surgical procedures used to treat these three cancers (radical prostatectomy, radical cystectomy and radical nephrectomy, respectively) were selected for study in this thesis as they represent relatively common procedures, with different surgical complexities and variable physiological impact on the patient, and consequently utilise differing degrees of hospital critical care facilities.

Section two presents a general overview of routinely collected administrative data with particular reference to the HES database. This section also describes a methodological component of work within the HES database whereby a case-mix adjustment score that utilises information on disease comorbidities obtained in part from hospital admissions over the year preceding admission for surgery was developed. This score is used in subsequent chapters of the thesis and is the first time that a validated case-mix adjustment score has been developed within the HES database that allows for a degree of risk adjustment. At the time of writing this thesis, the HES database did not contain an index that could be widely used to adjust for patient case mix, although there were plans to incorporate the American Society of Anaesthesiology (ASA) score in the near future.

Section three presents a descriptive analysis of practice and outcomes for radical urological cancer surgery in England from administrative data extracted from the HES database. Within this section, the feasibility of using emergency hospital readmission rate as a measure of surgical outcome, in addition to the more easily identifiable outcomes of in-hospital mortality and length of hospital stay is explored.

Section four consists of three chapters that describe differing aspects of 'volume and outcome' realationships within radical urological cancer surgery. Firstly, a systematic review and critique of the literature relating procedural volume to post-operative outcomes following radical urological cancer surgery is presented. Secondly, the results of a national survey of consultant urological opinion relating to volume and outcome relationships with respect to these procedures are described. Using the data and methodology developed in sections two and three, this section concludes by presenting a study that examines the relationships between the number (or 'volume') of cases undertaken by a hospital and the outcomes attained following surgery. To the best of available knowledge, this is the first time that volume and outcome relationships have been studied on a national basis using HES data in England.

Finally, the *a priori* aims of this thesis were firstly to describe the practice and outcomes for radical urological cancer surgery in England and secondly, to determine whether the number (or 'volume') of procedures that a hospital carries out is a potential determinant of these outcomes. To what extent the data and studies presented in this thesis have achieved these aims is discussed within the final chapter (section five). There is some overlap between sections and chapters and where necessary cross-references have been given.

1.2 Background to thesis

Large quantities of healthcare information are contained within local and national databases of routinely collected data. These clinical data can be broadly classified into two groups. The first has been described as 'routine data' that is collected irrespective of the procedure or outcome. [Bain M et al, 1997] Examples of routine data include: data collected on deaths, births, and stillbirths; cancer registry data; statutory notifications of infectious diseases; and Hospital Episode Statistics (HES). [Department of Health, 2000] HES are currently collected on every NHS hospital admission in England. The second group of data refers to that which is collected with a specific purpose in mind. Most audit and research projects fall into this group. A protocol is written and a data collection proforma results. This is used to capture the data elements that are required for a particular project. An example is the UK National Prostatectomy Audit. [Emberton M et al, 1995]

Advantages of the use of routine data are their relatively low cost as the procedures for data collection are already in place; large database size, which reduces the chance of sampling errors; large population coverage; and collection usually spans a significant time period, which allows for patterns and trends to be elucidated. Routinely collected data predominantly arise from the administration of healthcare delivery and as such the main producers of such data are national governments and insurance providers. Apart from patient demographic data, these databases often contain information on the presence of comorbid disease and on medical procedures that have been undertaken. Partly due to their comprehensive size, these data have often been used to evaluate the quality of healthcare – a purpose for which they were not primarily designed.

It is generally assumed that the second group of databases is the most useful for research and audit purposes as the data collected is specific for purpose and the quality of the data can be estimated. However, the cost of collecting data in this way remains high. Moreover, because it is limited to the question being addressed it can only be used in a finite number of ways. Therefore, there has been considerable interest in taking a further look at routine datasets and building on these to answer important clinical questions. [Lewsey J et al, 2000; McKee M et al, 1997]

Complete, timely and accurate data are needed to monitor the quality of surgical care in the UK, both within the NHS and within the independent healthcare sector. However, large-scale national audits to collect data on the quality of care are labour-intensive and therefore considerably expensive. It is therefore important to consider alternative approaches to provide data of adequate quality at relatively low cost across the breadth of surgery. Furthermore, improving the quality of care is at the heart of the NHS modernisation agenda. To achieve quality improvement, a robust and efficient framework to monitor the quality of surgical care is required, as well as a systematic approach to identify factors that contribute to variations in quality. Currently, the information on the quality of surgical care is predominantly generated by relatively small ad hoc studies. Many of these studies are carried out by the surgical specialty associations with limited funding and often without essential resources and support. Recently, a small number of national audits were initiated and funded by the Commission for Healthcare Improvement – and its successor the Healthcare Commission – that predominantly address NHS priorities (e.g. cancer and coronary heart disease). [Healthcare Commission, 2004] These audits are large and labour-intensive projects. Understandably, only a limited range of surgical problems and interventions can ever be investigated in this way.

In the US, a growing number of studies on the quality of surgical care are published based on administrative data. [Birkmeyer J et al, 2003; Begg C et al, 2002] An administrative database that is often used in the US is the Medicare database. This database encompasses the Medicare claims of 97% of individuals aged 65 or older. The HES database, funded and managed by the Department of Health in England, contains information about all admissions to NHS Trusts, and could be considered as an English equivalent.

In contrast to its American counterpart the HES database is infrequently used. There are several explanations for this. First, an obvious explanation is that there are concerns over the completeness and accuracy of the HES data, although there is limited evidence to underpin this. Furthermore, these concerns are often based on historical inaccuracies or poor understanding of the uses to which routine data can be put. For example, a recent systematic review including studies comparing HES records with case notes in the UK only retrieved studies that examined the period before the introduction of the ICD-10 in 1995. [Campbell S et al, 2001] Most of these studies used methods of variable quality, were performed in a limited number of centres, and included a small number of patients. Second, the HES database is less detailed than the databases used in the US because the latter are generated as a component of a prospective payment system. [McKee M et al, 1997] A complicating factor is that in the UK the ICD-10 and the OPCS-4 coding systems are used to code diagnoses and procedures, whereas in the US both diagnoses and procedures are currently coded according to the clinically modified version of the ICD-9 (see chapter 3). [World Health Organisation 1977, 1994; Office of Population Censuses and Surveys, 1996] Third, comparisons (among providers or between different types of treatment) based on HES data may be misleading as the HES database contains only limited information on disease severity and comorbidity. [Michaels J, 2003] A number of US studies applied a system to identify comorbidity from admissions to hospital preceding the admission for surgery (see chapter 4). [Birkmeyer J et al, 2002] This system has never been applied in the UK. An evaluation of the impact of adjusting for comorbidity is crucial as some studies based on administrative data show clinically implausible results (presence of comorbidity is associated with better outcomes). [Finlayson E et al, 2002]

As a consequence of these perceived problems, policy makers in the UK often have to use American studies if they are developing approaches to improve the quality of surgical care in the UK. [National Institute of Clinical Excellence, 2002] For example, in the field of urological cancer surgery, the only available national data are provided by a voluntary registry maintained by the British Association of Urological Surgeons (BAUS) since 1998. However, this registry does not collect information on any outcomes, although sub-samples have been followed up for specific audit and research projects. [Directory of Clinical Databases, 2004] It was estimated that in 2002 only 62% of all urological cancers were included in the BAUS registry and that only 26% of the variables (8 out of 30) had a high level of completeness (>95%). Recently however, the registry has started to collect more detailed information on diagnosis and staging as well as on outcomes in the first year after surgery. It is therefore not surprising that the guidance on urological cancer services issued in 2002 by the National Institute of Clinical Excellence (recommending that surgical treatment for urological cancer should be centralised in units that treat a high number of patients per year) is predominantly supported by evidence from the US.

Within the field of surgery, many studies have noted wide variation between post-operative outcomes at different hospitals and by different surgeons. [Porter G et al, 2000, Dixon T et al, 2004] Studies have also tried to determine whether the number of cases performed either by a surgeon or hospital is one component that can influence the outcomes obtained following surgery (see Chapter 7). Conducting a randomised controlled clinical trial to answer questions relating to volume and outcome relationships would entail significant costs, and may be difficult to obtain ethical approval. Practical difficulties may also ensue in relation to trial recruitment. Furthermore, the results may not be generalisable as any randomised controlled trial would have to be conducted within a limited setting. [Porter G et al, 2000] Large database analyses that cover large populations have been used to try to answer such questions in the past. [Iezzoni L, 1990; Gerszten P, 1998] Therefore, using methodological components developed within earlier chapters, this thesis concludes with a clinical component exploring whether for radical urological cancer surgery the volume of surgical cases undertaken by hospitals in England influences the outcomes achieved.

In summary, evaluation of the quality of healthcare is of increasing interest for patients, politicians, policy-makers and healthcare professionals. Evaluating healthcare quality on a national level will help to identify areas where quality might be suboptimal as well as provide benchmark data against which local providers can compare themselves. Implementation of nationwide policies aimed at improving the quality of healthcare demand that the success or otherwise of these policies is determined. At the same time this needs to be achieved within the context of limited financial resources. Rich sources of data, such as Hospital Episode Statistics, offer many practical advantages in assessing the quality of care. [Bloor K et al, 2004] These databases are an efficient way of providing clinicians, patients and health service researchers with up-to-date information. However, further work is required in order to demonstrate the potential of these databases, to examine the quality of their data, and to improve their design to ensure their clinical effectiveness.

In response, the Clinical Effectiveness Unit (CEU) at the Royal College of Surgeons of England has developed a programme of work to evaluate the feasibility and validity of using HES data to evaluate the quality of surgical care, and this thesis for the Degree of Doctor of Medicine presents part of this work that aims to redress these deficiencies. This programme of work has the potential to help to improve the quality of hospital care across the UK in general, and for patients with urological cancer in particular, as it will evaluate the HES database as a resource of information on surgical process and outcome.

1.3 Practical considerations

For the purposes of this project, the Clinical Effectiveness Unit (CEU) established a collaboration with the HES Section of the Department of Health. The Director (Dr Jan HP van der Meulen) and the Clinical Director (Mr Mark Emberton) of the CEU appointed a research fellow (Mr Martin Nuttall), who had completed basic surgical training, who would be responsible for the day-to-day management and coordination of the project for two years. An Advisory Group of interested parties was also assembled to advise in the conduct of this study (Appendix 1). The entire study was funded by the Bob Young Research Fellowship and the Research Fellowship Scheme of the Royal College of Surgeons of England.

The Clinical Effectiveness Unit at the Royal College of Surgeons of England is an academic collaboration between the Health Services Research Unit of the London School of Hygiene and Tropical Medicine of the University of London and the Royal College of Surgeons of England. It is the remit of the CEU is to study "the epidemiology of the quality of surgical care". The CEU was established in 1996, replacing the Surgical Audit and Epidemiology Unit, which was one of the leaders in the field of developing surgical audit methodology.

The vast majority of the work in this thesis has been undertaken by me. However, in the course of conducting this work, I worked within a team with my supervisors, Mr Emberton and Dr Van der Meulen, whereby all three of us contributed ideas to this work. I performed all of the analyses presented in this work, although statistical and methodological guidance was provided by Dr Van der Meulen. All literature searches and background research were conducted by me, and the entire text has been written by me under the guidance of my two supervisors. This thesis represents original work, although some aspects of this work have been based on methods used by other workers, and where this is the case appropriate references have been provided.

Chapter 2

Description of the treatment options available for the three urological malignancies – cancer of the prostate, kidney and bladder

2.1 Objectives

The objectives of this chapter are to describe in brief the epidemiology, methods of diagnosis, and treatments available for localised carcinoma of the prostate, muscle-invasive carcinoma of the bladder and localised carcinoma of the kidney as background information for readers of this thesis.

2.2 Description of epidemiology, diagnosis and treatment for localised carcinoma of the prostate and radical prostatectomy

2.2.1 Epidemiology and risk factors

Prostate cancer is the second leading cause of death within men, after lung cancer, within the western world and public awareness of this disease is increasing through widespread coverage within the lay press. Each year in the United Kingdom about 10,000 men die from prostate cancer. In the United States, the American Cancer Society estimated that in 2001, 184 500 new cases of prostate cancer were diagnosed and 39 200 men died of this disease. It has been estimated that 30% of men will develop prostate cancer during their lifetime. It is therefore an important health problem. Prostate cancer is primarily a disease of men aged over 50 years with half of all registered cases occurring in men over 75 years and 95% in men over 60 years. [Cancer Research UK, 2002] However, although by the age of 80 around 65% of men will have prostate cancer, only about 1 in 30 of these men will die of this prostate cancer. [Selly et al, 1997] The lifetime risk of dying from prostate cancer is approximately 3%.

Between 1971 and 1999, both the registration and the mortality rates of prostate cancer have been increasing in England and Wales. However, this may in part be associated with the advent of PSA testing in the 1990s. Furthermore, the aging population means that the number of men with prostate cancer will be expected to increase markedly during the next two decades. [Chamberlain et al, 1997]

There is a both a racial and a genetic predisposition for the development of carcinoma of the prostate. In the US, African-Americans have a higher risk for developing prostate cancer than whites and they also have a higher mortality associated with the disease. For men with one first degree relative with prostate cancer, the risk of developing prostate cancer is increased two-fold. This increases to nine-fold if two first-degree relatives are affected with the disease. A familial tendency is also associated with men who develop prostate cancer aged less than fifty years. [McLellan et al, 1995] There is also a marked geographical variation in the incidence of prostate cancer – the risk being highest in North America and northern Europe and lowest in the Far East. Chinese and Japanese races have the lowest incidence of prostate cancer. In migration studies, the incidence of prostate cancer changes to that of the local population.

Another factor associated with the development of prostate cancer is an elevation in serum testosterone level. A recent meta-analysis showed that men with serum testosterone levels in the highest quartile are over twice as likely to develop prostate cancer as those in the lowest quartile. Likewise, high levels of insulin-like growth factor are associated with a similar increase in risk. [Shaneyfelt et al, 2000] However, a systematic review refuted the suggestion that a previous vasectomy was associated with a higher risk of prostate cancer. [Bernal-Delgado et al, 1998]

Increased risk of prostate cancer is also associated with diets high in animal fats but the underlying pathophysiology of this association remains unexplained. [Kellerbyrne J et al, 1997] On the other hand, however, diets which include a high intake of vegetables rich in carotenoids, such as tomatoes, and fish appear to be protective. [Dijkman G et al, 1996, World Cancer Research Fund, 1997; Cohen J et al, 2000] Finally, prostate cancer has also been associated with exposure to low levels of ultraviolet light, which may be due to a protective effect of vitamin D related to sunlight exposure.

2.2.2 Diagnosis, Grading and Staging

Men with clinically significant prostate cancer usually present with a combination of weight loss, lethargy, bone pain and lower urinary tract symptoms secondary to bladder outflow obstruction caused by locally advanced disease. However, men are increasingly being diagnosed with this disease at a much earlier stage when they are asymptomatic.

Several techniques are used to diagnose prostate cancer. Firstly, digital rectal examination (DRE) may detect those prostatic cancers lying within the peripheral zone of the prostate. This technique will detect prostate cancer in asymptomatic men in 0.1-4% of those examined. [Chodak G, 1989; Pedersen K et al, 1990] This technique is, however, very dependent on the experience of the practitioner and only about one third of palpable nodules are confirmed as malignant when examined histologically.

Secondly, the determination of serum prostate specific antigen (PSA) level has revolutionalised both the diagnosis and treatment of prostate cancer. [Oesterling J, 1991] PSA is a serine protease produced almost exclusively by the epithelial cells of the prostate and is responsible for the liquefaction of semen. However, PSA is not disease specific, it being elevated by prostatitis, instrumentation of the urinary tract, benign prostatic hypertrophy and other non-malignant prostatic conditions. Determination of serum PSA is also useful for assessing the response to treatment. In order to increase the diagnostic accuracy of PSA testing, several different measurements of PSA have become established. These include PSA density, PSA velocity, age-specific reference ranges, and different isoforms of PSA.

Thirdly, transrectal ultrasound (TRUS) can be used to diagnose prostate cancer, where classically a hypoechoic area is seen in the peripheral zone of the prostate. TRUS is also able to improve the accuracy of prostatic biopsy and this has become the standard method of obtaining tissue for histological diagnostic confirmation, in preference to digitally guided prostatic biopsies. Finally, prostate cancer may incidentally be diagnosed on men undergoing transurethral resection of the prostate for benign prostatic hyperplasia, when the resected prostatic chippings are subject to histological analysis.

The most commonly used histological grading system for prostate cancer is the Gleason system. [Gleason D et al, 1977] This system is based on a low-power microscopic description of the cancer. A Gleason grade of 1-5 is assigned to the pattern occupying the greatest area of the specimen and this forms the primary grade. A secondary grade is assigned to the area occupying the second largest area of the specimen. The Gleason sum (2-10) is determined by adding together these two scores. A Gleason grade of ≥4 or a sum of ≥7 is a predictor of a poorer prognosis. [Stein et al, 1991; Zincke H et al, 1994]

The goals of staging prostate cancer are to evaluate prognosis and to direct rationally therapy based on the extent of disease. Disease stage is determined using the 2002 TNM (Tumour Node Metastasis) disease classification (table 2.1). This assessment is usually performed by a combination of digital rectal examination, PSA level, and bone scan, supplemented with computed tomography (CT) scanning or more recently, magnetic resonance imaging (MRI). [Aus G et al, 2003] Accurate grading and staging of prostate cancer are essential prerequisites to the identification of patients who may benefit from radical treatment.

The tumour stage represents the pathological extent of disease. For the 'T' stage, T1 represents incidental disease; T2-3 intermediate disease; and T4 advanced disease (table 2.1). Clinical progression is assessed by a combination of the 'N' and 'M' stages. Metastatic disease is most commonly found in lymph nodes and bones.

A combination of serum PSA level, tumour grade and digital rectal examination can be used to estimate clinical 'T' stage and is more useful than these parameters considered individually. [Partin A et al, 2001] TRUS does not, however, view the prostate with sufficient accuracy to be used as a routine staging tool. Similarly, neither CT or MRI scanning are of sufficient accuracy to be used routinely for staging purposes, although the use of MRI in particular is increasing. [Lee N et al, 1999; Jager G et al, 2000]

Investigations to determine 'N' stage were usually performed when radical treatment was planned, but are now used less on the basis of increasingly restrictive criteria for case selection. The 'gold standard technique' for determining the 'N' stage is lymph node biopsy, performed either as an open or a laparoscopic procedure. Positron emission tomography (PET) has also been used to evaluate lymph node status but this technique is at a relatively early stage of development. [Sanz G et al, 1999]

Bone scintigraphy is the most accurate method to determine the presence of bone metastases, which are present in 85% of patients dying from prostate cancer. [McGregor B et al, 1978; Whitmore W, 1984] Serum PSA>100 ng/ml also has a positive predictive value for the presence of bony metastases of 100%. [Rana A et al, 1992] For non-bony metastases, chest x-ray, CT or MRI scanning are additional methods of investigation. However, for asymptomatic patients with a serum PSA<20 ng/ml and either a well or moderately differentiated tumour, a bone scan is not indicated. [Oesterling J, 1993]

2.2.3 Treatment of localised disease

The treatment of localised early stage prostate cancer is controversial for several reasons. First, there are a number of differing therapies available. Second, there is a high incidence of comorbidity in this population and last, there is substantial heterogeneity in disease behaviour and progression between patients.

There are a number of surgical and non-surgical treatment options available for localised carcinoma of the prostate. The surgical options are radical retropubic prostatectomy, radical perineal prostatectomy, and laparoscopic radical prostatectomy. The non-surgical treatment options include conformal and external beam radiotherapy, brachytherapy, high intensity focussed ultrasound and cryotherapy. Finally, it is also important to consider the concept of 'watchful waiting' or 'active surveillance' as a treatment option for some men with prostate cancer.

Exact preoperative staging should identify men with organ-confined disease and suitable for potential curative treatment with radical therapy. [Huland H et al, 1994] In addition, over recent years a number of pre-treatment nomograms have been developed that help to predict patient outcomes following radical prostatectomy. [Partin A et al, 1993; Partin A et al, 1996] Patients selected for radical prostatectomy should have a life expectancy of at least ten years; prostate cancer localised to the prostate gland; and have no severe comorbidity.

2.2.4 Radical Prostatectomy

Radical prostatectomy is defined as the removal of the prostate gland in its entirety together with the seminal vesicles. Radical prostatectomy is the most reliable method of preventing the progression of localised prostate cancer. The first radical prostatectomy was performed through a perineal approach in 1866 by Theodore Bilroth. However, the operation was slow to gain in popularity because of its considerable mortality. In 1905 Hugh Hampton Young described a technique to carry out this procedure with a much lower mortality rate (17%). There were still considerable and common complications to be overcome, including urethral strictures and fistulae, impotence and incontinence.

The retropubic approach to radical prostatectomy was developed by Terence Millin following his original description of his classical operation for benign disease. [Memmelaar J et al, 1949] However, the risk of uncontrolled haemorrhage from

Santorini's plexus remained with the retropubic approach. In 1979 Patrick Walsh described a surgical technique to control Santorini's plexus that allowed radical retropubic prostatectomy to be accomplished with a considerably lower risk of haemorrhage. Other consequences of this were a relatively bloodless field that allowed more accurate apical dissection of the prostate and preservation of the urethra. Walsh also described the course of the neurovascular bundles and the importance of their preservation for recovery of erectile potency following surgery. [Walsh P et al, 1982; Walsh P et al, 1983; Lepor H et al, 1985] These two contributions led to the description of the 'anatomical' radical retropubic prostatectomy that is in routine use today. [Walsh PC, 1998; Walsh PC et al, 1987]

The predominant morbidity of radical retropubic prostatectomy relates to erectile dysfunction. Although, other complications include urinary incontinence, anastomotic stricture, bleeding, lymphocele, and rarely, rectal injury and pulmonary embolism. The main goals to achieve following radical prostatectomy are cancer control, preservation of continence and preservation of potency. [Kirby R, 2004]

The radical perineal prostatectomy is preferred to the retropubic approach by some surgeons, partly as the dorsal venous complex is avoided. Complications that are related to this approach include anal and rectal injury, faecal incontinence and rectal fistulae. The perineal approach does not allow the sampling of lymph nodes and if this is required, this is done as separate procedure before the definitive procedure.

Laparoscopic radical prostatectomy was first described in 1992. [Schuessler W et al, 1997] Advantages of this technique include reduction in the extent of surgical incisions, reduction in post-operative pain, decreased blood loss and shorter length of stay.

However, specific skills are required and this procedure is currently only available in a few centres in the UK. Technical ability and experience influence operative time considerably and this can be very prolonged during the initial stages of the learning curve. [Guillonneau B et al, 2000; Bollens R et al, 2002]

Radical prostatectomy is primarily performed to achieve long-term disease free survival and cure from localised prostate cancer. [Han M et al, 2001] It is now known that sparing of the neurovascular bundles does not compromise cancer cure rates and indeed now bilateral excision of the neurovascular bundles is rarely performed, which therefore maximises the chances of functional recovery of potency. [Walsh P et al, 1987] Small variations in surgical technique can also influence potency rates. [Walsh P et al, 2000] Urinary incontinence following radical prostatectomy is relatively rare and most patients will be continent after two years. Post-operative continence is thought to be related to sphincteric or neurogenic damage during surgery, loss of urethral or bladder neck support and periurethral fibrosis. Sparing of the neurovascular bundles may also contribute to preservation of urinary continence.

Radical prostatectomy when performed by experienced surgeons can maintain excellent quality of life. However, there are differences in reported outcomes between centres. Furthermore, to assess consistently and validly potency or continence rates between centres is difficult, and there are also differences between centres in terms of patient age and degree of comorbidity. [Fowler F et al, 1993; Talcott J et al, 1998] Individual training and experience may also be significant factors in influencing patient outcomes. [Eastham J et al, 2003]

In summary, radical prostatectomy is a safe treatment that can achieve cure from localised prostate cancer with good quality of life. There are several approaches to perform this procedure, although currently radical retropubic prostatectomy remains the 'gold standard'. [Kirby R, 2004] The advances in surgical technique achieved over the last one hundred years emphasise the importance of surgical skill in achieving good outcomes following this procedure.

2.3 Description of epidemiology, diagnosis and treatment for muscle-invasive carcinoma of the bladder and radical cystectomy

2.3.1 Epidemiology and risk factors

Bladder cancer is a very common disease seen in both the community and in the hospital settings. There are several differing types of bladder cancer that exhibit differing patterns of behaviour. However, most cases are transitional cell carcinomata (approximately 90%) and tend to occur as either low grade superficial tumours or high grade muscle-invasive tumours.

Bladder cancer occurs approximately three times more commonly in males as in females. There are approximately 55,000 new cases of bladder cancer diagnosed annually in the US and around 11,000 annually in the UK. [Boring C et al, 1995; Cancer Research Statistics UK, 2000] Approximately 5000 people die of bladder cancer each year in the UK. [Cancer Research Statistics 2000, UK] The incidence of bladder cancer increases with age and is about twice as common in white men compared to black men and about 1.5 times as common in white compared to black women. [Annual Cancer Statistics Review, 1987] Bladder cancer is the fifth most common cause of death in men. [Boring C et al, 1995] Over the last fifty years, the incidence of bladder cancer has increased by about 50% but the mortality rate over this time period has decreased by about one third. [Annual Cancer Statistics Review, 1987] There are geographical variations in the incidence of bladder cancer. For example, that reported in the UK and the US is higher than that reported in Finland and Japan. [Morrison A, 1984]

There are several risk factors associated with the development of bladder cancer. These include exposure to aniline dyes and aldehydes in manufacturing and chemical industries. These are typically associated with long periods of time between exposure and clinical symptoms. Aromatic amines used in printing, plumbing and dry cleaning industries are also bladder carcinogens. [Morrison A, 1984] Several of these industries, where the risk of exposure to these carcinogens is high, have set up screening programmes for the early detection of bladder cancer or its precursors.

Cigarette smoking is one of the most common risk factors associated with the development of bladder cancer – the risk is about four times higher in smokers than non-smokers. The risk increases with the number of pack years smoked and decreases over time when smoking is stopped. [Augustine A et al, 1988] The use of large quantities of analgesics containing phenacetin has also been connected with an increased risk of developing bladder cancer. [Piper J et al, 1985] Conditions associated with the development of chronic cystitis such as long-term catheters, bladder stones and infection with *Schistosoma haematobium* have been linked to the development of squamous cell carcinoma of the bladder. Finally, although there have been sporadic reports of familial clusters of bladder cancer, there is no definitive evidence of a hereditary nature to this disease. [McCullough D et al, 1975]

2.3.2 Diagnosis, Grading and Staging

The majority of cases of bladder cancer are detected following cystoscopy for either micro or macroscopic haematuria. Other symptoms that have been associated with the presence of bladder cancer include the lower urinary tract symptoms of urgency, frequency and dysuria. For more advanced disease, symptoms include weight loss, flank pain and generalised malaise.

Microscopic cytological examination of the urine is often used to detect malignant transitional cells of the urinary tract, although a negative test does not exclude the presence of carcinoma. Cystoscopy, either under local or general anaesthetic, is performed on any patient suspected to have a diagnosis of bladder cancer. Any abnormal areas of the bladder seen on cystoscopy are usually biopsied and sent for histological analysis. As bladder cancer can affect the entire urothelium, any patient with abnormal urine cytology or cystoscopic examination should have the upper urinary tracts visualised. This is normally performed using intravenous urography or in some cases with retrograde ureteropyelography.

The most commonly used systems to grade bladder carcinoma are based on the degree of anaplasia of the tumour cells. For example, bladder cancer may be graded 1-3 on the basis of whether the tumour cells are well differentiated, moderately differentiated or poorly differentiated tumours, respectively. [Koss L, 1975] There is also a strong correlation between the grade of a tumour and its stage – most well or moderately differentiated tumours are superficial and most poorly differentiated tumours are muscle-invasive – and also prognosis. Bladder cancer can only be staged by using a combination of clinical and histological means. Most patients will therefore undergo a trans-urethral resection of their bladder tumour in order to provide histological specimens. The staging system in most common use is the TNM system (table 2.2)

As is the case with prostate cancer, tumour staging plays an important role in deciding on treatment for bladder cancer. Most patients with superficial, low grade disease will not undergo further staging investigations. However, for those with muscle-invasive disease, further tests are usually indicated. CT scanning is the most widely used investigation for this purpose and is performed to provide information regarding the presence of lymphadenopathy or metastatic disease. However sensitivity for detection of lymph node metastases is low. [Malmstrom P et al, 1993] Other imaging modalities in use for this purpose include MRI scanning and ultrasonography. Laparoscopic lymphadenectomy or CT-guided fine needle aspiration of lymph nodes have also been used to provide further information for the staging of bladder cancer. Finally, for the detection of metastatic disease, chest radiography or CT scanning of the thorax are usually performed.

2.3.3 Treatment of muscle-invasive bladder cancer

There are two main radical treatment modalities in use for muscle-invasive carcinoma of the bladder: radical surgery and radical radiotherapy. For patients undergoing radical surgery, a decision must also be reached with regard to bladder reconstruction or urinary diversion. Chemotherapy within either an adjuvant or neoadjuvant setting is now increasingly being used. [Stockle M et al, 1995; Herr H et al, 1998] There have been few trials of adequate power comparing the outcomes of radical radiotherapy and radical cystectomy. A recent UK study found no significant difference in five-year survival for patients treated with either radical radiotherapy or radical cystectomy, and both treatments were associated with significant morbidity and mortality. [Chahal R et al, 2003] Salvage cystectomy may be used in patients who have not responded fully to radiation treatment. [Bloom H et al, 1980]

2.3.4 Radical cystectomy

The main indication for radical cystectomy is muscle-invasive tumour, but it is also indicated for superficial tumours at high risk of recurrence or progression. The objective of the operation of radical cystectomy is to remove the bladder in its entirety, together with the pelvic lymph nodes. In men the standard treatment is also to remove the prostate, and in women an anterior pelvic exenteration is performed where the bladder, urethra, uterus, fallopian tubes, ovaries and anterior wall of the vagina are removed. In men, the urethra is not always removed during the initial surgery but there is a high chance of recurrent disease in the presence of involvement of the bladder neck or trigone or in patients with multifocal disease. Urethrectomy may therefore be performed as a subsequent procedure if the urethral resection margin is positive. [Stein J et al, 1994, Coloby P et al, 1994]

Relatively recently, the procedure of radical cystoprostatectomy was modified to include a nerve-sparing approach that attempts to preserve erectile potency, which is otherwise lost following this procedure. [Brendler C et al, 1990a] There is a degree of uncertainty regarding this modification as some lymph nodes may not be removed. However, initial experience with this procedure has been reported positively. [Brendler C et al, 1990b]

For patients in whom the urethra and urinary sphincter have not been removed, a low-pressure orthotopic bladder substitution can be constructed from bowel. This procedure is technically complex but most patients are able to achieve daytime continence, although many suffer from nocturnal enuresis. Alternatively, a continent urinary diversion can be created for patients in whom the urethra has been removed. This involves the construction of a urinary reservoir from bowel that can be drained via a continent catheterisable stoma on the abdominal wall. Again, these procedures are technically challenging and are associated with complications such as stone formation, stomal stenosis and urinary tract infections. The most straightforward approach to achieve urinary diversion, with the lowest complication rates, is the construction of a cutaneous diversion using a conduit. This is most commonly performed with an ileal loop. This approach is traditionally used for more elderly patients and in those who have the presence of a greater degree of comorbidity, as it is a technically simpler procedure to perform and is relatively simple to manage in the long-term, although complications relating to the stoma are relatively common. [Sullivan J et al, 1980]

Radical cystectomy and urinary diversion is associated with a high complication rate of between 17-32%. [Rosario D et al, 2000; Chahal R et al, 2003; Sullivan J et al, 1980] The most common complications include sepsis, thromboembolic disease and intestinal obstruction. Reoperation rates are also high following radical cystectomy (approximately 10%). [Wishnow K et al, 1989] However, there is evidence that mortality rates following radical cystectomy have fallen considerably over recent years and are now around 1-2% in some centres. [Rosario D et al, 2000]

2.4 Description of epidemiology, diagnosis and treatment for localised carcinoma of the kidney and radical nephrectomy

2.4.1 Epidemiology and risk factors

Renal cell carcinoma accounts for approximately 3360 deaths every year in the United Kingdom and approximately 6200 new cases are registered each year. [Cancer Research Statistics UK, 2000] The incidence in men is approximately twice that of the incidence in women and it occurs most commonly in those aged between the sixth and seventh decades. Cigarette smokers are at an increased risk of developing renal cell carcinoma. The incidence also appears to be higher in workers exposed to lead, asbestos and cadmium. [Kolonel L et al, 1976] The incidence is also higher in patients with von Hippel-Lindau syndrome (cerebral and retinal haemangiomas). Renal cell carcinomata represent about 90% of malignant tumours of the kidney.

2.4.2 Diagnosis, Grading and Staging

The most common presenting symptom in patients with renal cell carcinoma is haematuria. The 'classic' triad of symptoms of loin pain, haematuria and palpable flank mass occurs rarely. Symptoms of more advanced or metastatic disease include weight loss, fever and hypercalcaemia. With the wide availability of ultrasound and CT scanning, more renal cell tumours are now detected incidentally and at an earlier stage. Ultrasound scanning can discriminate between solid and cystic lesions in the kidney – any abnormality that cannot clearly be defined as a simple cyst requires further imaging with the aid of a CT scan. CT scanning is now the diagnostic method of choice for imaging renal masses. [Newhouse J, 1993] Furthermore, CT scanning allows more accurate staging of renal tumours than ultrasound scanning and in terms of diagnostic accuracy is similar, but much less invasive, than angiography. Extension of tumour into the renal vein or the inferior vena cava can also be determined, as well as the degree of tumour invasion into adjacent structures. [Lang E, 1984] To complete preoperative staging, liver function tests, serum calcium measurement and chest radiography are normally performed to detect metastatic disease. Approximately one quarter of patients have metastatic disease at presentation. [Johnson J et al, 1997]

There are a number of staging classification systems in use for renal cell carcinoma. The Robson staging system has now been superceded in many centres by the TNM classification (table 2.3). CT scanning can estimate the clinical stage but the final staging process is not complete until after surgical excision and pathological assessment. Final tumour stage is the most important predictor of survival, although tumour grade is also a predictor. [Medeiros L et al, 1988]

2.4.3 Treatment of localised carcinoma of the kidney

Surgery offers the only chance of cure to patients with renal cell carcinoma, with cure dependent on the stage and grade of the tumour. The operation most commonly performed in the UK is a radical nephrectomy, which entails the removal of the kidney, its surrounding perinephric fat, Gerota's fascia and regional lymph nodes. This procedure may be performed either by an open approach or, increasingly, by a laparoscopic approach. Renal sparing surgery, or partial nephrectomy, may also be offered, particularly to patients with a solitary kidney or patients with tumours <4cm in diameter and near the periphery of the kidney. Occasionally nephrectomy is performed as a palliative treatment together with other therapies such as immunotherapy. [Figlin R, 1999]

2.4.4 Radical nephrectomy

There are several different anatomical approaches that may be used in order to perform a radical nephrectomy. The flank approach is the most commonly used in the UK and avoids entering the peritoneal cavity. However, compared to the anterior trans-abdominal approach, access to the renal vascular pedicle is not as good. The trans-abdominal approach has the disadvantage of increasing the chances of developing post-operative ileus and the risk of developing peritoneal adhesions. A thoraco-abdominal approach is occasionally used for extensive tumours of the upper pole of the kidney or for tumours with invasion of the inferior vena cava.

One of the guiding surgical principles of radical nephrectomy is removal of the kidney and Gerota's fascia. The ipsilateral adrenal gland need not necessarily be removed unless the tumour involves the upper pole of the kidney. [Sagalowsky et al, 1994] The need for accurate preoperative staging cannot be over-emphasised as this will dictate the operative approach and, in cases of involvement of the vena cava, dictate whether vascular or cardiothoracic surgeons should also be involved with the procedure.

The complications following radical nephrectomy are influenced by the choice of surgical approach and, as with other operative procedures, the degree of comorbid disease present within the patient. One of the most common complications is haemorrhage. Other complications include injury to abdominal organs such as the spleen, pancreas or bowel and systemic complications such as thromboembolic disease and pneumonia.

2.5 Tables

Table 2.1: Tumour Node Metastasis classification for cancer of the prostate

T	**Primary tumour**
Tx	Primary tumour cannot be assessed
T0	No evidence of primary tumour
T1	Clinically unapparent tumour not palpable or visible by imaging
T1a	Tumour incidental histological finding in ≤ 5% of resected tissue
T1b	Tumour incidental histological finding in >5% of resected tissue
T1c	Tumour identified by needle biopsy
T2	Tumour confined within the prostate
T2a	Tumour involves half or less of one lobe
T2b	Tumour involves more than half of one lobe
T2c	Tumour involves both lobes
T3	Tumour extends through prostatic capsule
T3a	Extracapsular extension
T3b	Tumour invades seminal vesicles
T4	Tumour is fixed or invades adjacent structures other than seminal vesicles: bladder neck, external sphincter, rectum, levator ani and/or pelvic wall
N	**Regional Lymph Nodes**
Nx	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Regional lymph node metastasis <2cm
N2	Regional lymph node metastasis 2-5cm
N3	Regional lymph node metastasis >5cm
M	**Distant Metastasis**
Mx	Distant metastasis cannot be assessed
M0	No distant metastasis
M1	Distant metastasis
M1a	Non-regional lymph nodes
M1b	Bone
M1c	Other sites

[TNM Classification, 2002]

Table 2.2: Tumour Node Metastasis classification for cancer of the bladder

T	**Primary tumour**
Tx	Primary tumour cannot be assessed
T0	No evidence of primary tumour
Tis	Carcinoma in situ
Ta	Non-invasive papillary tumour
T1	Tumour invades subepithelial connective tissue
T2	Tumour invades muscle
T2a	Tumour invades superficial muscle (inner half)
T2b	Tumour invades superficial muscle (outer half)
T3	Tumour invades perivesical tissues
T3a	Microscopically
T3b	Macroscopically
T4	Tumour invades prostate, uterus, vagina, pelvic or abdominal wall
N	**Regional Lymph Nodes**
Nx	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Single positive lymph node <2cm diameter
N2	Single positive lymph node >2cm but less then 5cm in diameter or multiple positive nodes <5cm in diameter
N3	Multiple positive nodes >5cm in diameter
M	**Distant Metastasis**
Mx	Distant metastasis cannot be assessed
M0	No distant metastasis
M1	Distant metastasis

[TNM Classification, 2002]

Table 2.3: Tumour Node Metastasis classification for cancer of the kidney

T	Primary tumour
Tx	Primary tumour cannot be assessed
T0	No evidence of primary tumour
T1	Tumour <7cm and limited to the kidney
T1a	Tumour <4cm
T1b	Tumour >4cm
T2	Tumour >7cm and limited to the kidney
T3	Tumour extends into major veins or adrenal gland or perinephric tissues but not beyond Gerota's fascia
T3a	Tumour invades adrenal gland or perinephric tissues but not beyond Gerota's fascia
T3b	Tumour grossly extends into renal vein or vena cava below diaphragm
T3c	Tumour grossly extends into vena cava above the diaphragm
T4	Tumour invades beyond Gerota's fascia
N	**Regional Lymph Nodes**
Nx	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in a single lymph node <2cm diameter
N2	Metastasis in a single lymph node >2cm but less then 5cm in diameter or multiple lymph nodes <5cm in diameter
N3	Metastasis in a lymph nodes >5cm in diameter
M	**Distant Metastasis**
Mx	Distant metastasis cannot be assessed
M0	No distant metastasis
M1	Distant metastasis

[TNM Classification, 2002]

Section 2

The HES Urological Cancer Dataset: Descriptive Analysis and Methodological Components

Chapter 3

The Hospital Episode Statistics Database

3.1 Introduction

The Hospital Episode Statistics (HES) database contains personal and medical information regarding all patients admitted to NHS hospitals in England. [Department of Health, 2000] The HES database was established in 1989, replacing the Hospital Activity Analysis (HAA) itself established in 1970. [Rowe R et al, 1972] Over 12 million records are collected and assembled each year. These include details of private patient admissions in NHS hospitals but not those in private hospitals. Data regarding outpatient attendances are not collated by HES.

The database was originally established with the aims of its use in policy development, in illustrating variations in health status and delivery with time and between geographic areas, in medical research, in assessing performance, and in determining the distribution of taxpayers' money on health care. [Hansell A et al, 2001] However, there has recently been a change of emphasis with greater resources now devoted to recording clinical data.

Data from Northern Ireland, Scotland and Wales are collected separately. In Wales the Patient Episode Database for Wales (PEDW) replaced the Welsh HAA in 1990. In Northern Ireland the Information and Analysis Unit of the Department of Health, Social Services and Public Safety for Northern Ireland replaced the Research and Intelligence Unit in collecting Hospital Statistics, and in Scotland in 1961, Scottish Morbidity Records (SMR) were established. The quality of health service information has traditionally been stronger in Scotland than in any of the other home nations and indeed Scotland has had quality assurance systems in existence for longer than the other nations. [Merry P, 1994] However, audits are conducted regularly to assess and monitor the quality of the HES database by the Department of Health. [Campbell S et al, 2001, Department of Health, 2001]

Within HES, each patient record is divided up into a number of data fields. These include basic demographic and administrative data, details regarding a patient's method of admission to hospital, clinical data referring to the admission including operative and diagnostic details, and details of discharge. The HES database has evolved over time, with new fields being introduced every year and therefore it can be problematic to compare certain data-years. Many of these items form part of the National Commissioning Data Set (CDS), and are generated by the patient administration systems within each hospital. In addition to the CDS items, HES provides information that is derived from the CDS items. For example, the age of a patient is derived from the date of birth. Data routinely collected on all admitted patients to NHS hospitals by local healthcare providers are submitted to the NHS-Wide Clearing Service (NWCS) and it is from the NWCS that the Department of Health collects data for the HES database. [Department of Health, 2000]

During every admission each patient is assigned to the care of at least one consultant, who is responsible for his or her treatment. The period of time under the care of a single consultant is referred to as a consultant episode. If the patient is under the care of more than one consultant during an admission, then there will be more than one consultant episode for that admission. One admission to hospital is referred to as a spell, which may therefore consist of several episodes.

If a patient is transferred to another hospital during an admission, the patient is considered discharged from the first hospital and then admitted to the second hospital. The discharge date from the first hospital is therefore the date of the last episode of the spell in the first hospital and the admission date to the second hospital is the first episode of the newly created spell in the new hospital. Since the 1997/1998 HES data-year it has been possible to link episodes or spells regarding the same patient by using the HES identification field HESID. For example, this allows data to be acquired describing readmissions following surgery. [Department of Health, 2000]

HES data are assembled into tables that are published each year by the Department of Health. Some data tables are published on the Internet (www.doh.gov.uk/hes) and other data are available on application to the Department of Health. Data are split into years that run from 1st April to 31st March. If a patient's admission does not finish in the same year as that in which it started, then that patient episode is described as unfinished and does not contain any medical data regarding that admission. A further episode is created for the year of discharge and it is this record, which contains the medical data regarding that admission. It is this record that should be used in clinical analyses.

HES data have been used to identify trends in healthcare, to negotiate funds and to allocate resources. [Central data collections from the NHS, 1998] They are increasingly used in clinical audit and in producing performance indicators, and may also be used in negotiating the new consultant contract and in doctors' appraisal. [The New NHS: modern and dependable, 1998; McKee M, 1993; Maynard A et al, 2001, Bloor K et al, 2004] Within the Department of Health, it is also used for financial planning, performance management and in the planning of service provision. Outside the Department of Health, customers include individual research groups, the National

Institute of Clinical Excellence, and the Audit Commission. The HES database is therefore very widely used.

The Department of Health is planning an expansion to the HES dataset with the inclusion of outpatient data in the future. Furthermore, has taken place to link HES data with mortality data from the Office of National Statistics as part of a larger programme of work improving the integration of national datasets. The concept of 'finished consultant episode' may also change in the future with the basic record of care moving towards a 'finished patient episode' to better reflect recent changes towards the multidisciplinary provision of healthcare. Currently, there is only provision within the HES database to record the General Medical Council code of the consultant responsible for the care of a patient. In the future it will be possible to include more data relating to clinicians such as the member of the team who performed a procedure as well as data relating to the anaesthetist. [Bloor K et al, 2004] In addition, it is also planned to include the American Society of Anaesthesiologists (ASA) classification score for all patients undergoing surgery to provide further data relating to patients' baseline physical status.

HES data can be accessed in a number of ways. [Hansell A et al, 2001] Firstly, the HES database can be accessed and inspected on-line. However, this is only available to selected users of HES. Secondly, published data tables may be freely inspected on the HES website. Thirdly, extracts from the HES database, specific to a user's requirements can be ordered directly from the Department of Health. A charge is normally levied for this service. Certain data fields are considered to contain sensitive data items and permission from the Security and Confidentiality Advisory Group (S&CAG) of the Department of Health may be required in order to receive these fields in an extract. Applicants are usually required to sign non-disclosure agreements and provide detailed documentation regarding data security policies at the institution where analysis of the data extract will occur. [Department of Health, 2000]

3.2 Clinical coding

Clinical data are identified from medical records following the discharge of a patient from hospital. This is a separate process from that of the National Confidential Enquiries or specialty-based audits. [Williams J et al, 2002] The process of data collection is summarised below. [Williams J et al, 2002]

1. Documentation in the medical record of all diagnoses made and procedures undertaken by the doctor.
2. Transfer of the medical record to the coding office following patient discharge from a clinical area by hospital management.
3. Dates of in-patient spell and finished consultant episodes (FCE) identified using NHS data definitions by the coder.
4. Identification of relevant diagnoses and procedures from the medical record by the coder.
5. Coding of primary diagnosis and subsidiary diagnoses and procedures by the coder.
6. Returns sent monthly to central office by hospital management.
7. Data aggregated and analysed by Department of Health.

There are clearly a number of steps at which the accuracy of HES data can be influenced. The accuracy of coding by trained coders when the underlying expression to code is unambiguous is high. [Walshe K et al, 1993; Colville R et al, 2000] This suggests that the predominant difficulty lies in the correct identification of either the diagnoses or procedures to be coded. [Cleary R et al, 2000] The involvement of clinicians in both responsibility for data collection and ownership of the data should improve data accuracy, [Yeoh C et al, 1993; Cleary R et al, 1994] but would involve a huge change in culture. [Williams J, 1998; Williams J, 2001] The need for clinicians to provide data on their practice for appraisal and revalidation may encourage this to change.

The HES database stores clinical data in the form of alphanumeric codes. Specific medical diagnoses are coded using the ninth revision of the International Classification of Diseases coding system (ICD-9) or subsequent to April 1995, the tenth revision of the International Classification of Diseases coding system (ICD-10). [World Health Organisation, 1977] The ICD-10 coding system, published in 1993, evolved from previous versions of the International Classification of Diseases. [World Health Organisation, 1994] The ICD-9 coding system had been in use in the NHS since 1979. Supplementary classifications, compatible with ICD have been developed for some specialties, to enable clinicians to record greater detail than available in the main ICD. The tenth revision (ICD-10) became mandatory in contract minimum data sets and central returns in the NHS in England on 1 April 1995. The coding system is maintained and published by the World Health Organisation. The ICD-10 is the latest in a series of disease classifications that were formalised in 1893 as the Bertillon Classification or International List of Causes of Death.

Operative procedures are coded using the fourth revision of the Offices of Populations Censuses and Surveys operative procedure coding system (OPCS-4). [Office of Population Censuses and Surveys, 1996] The OPCS-4 has evolved from a series of classifications revised since the earliest classification of surgical operations published in Britain by the Medical Research Council in 1944. Subsequent updates have been made to the fourth revision in 1987, 1988 and 1989. The classification is maintained and published by the NHS Information Authority. However, the classification is no longer meeting the needs of its users as current practice has significantly developed since the last revision of the OPCS coding system. Following a strategic review of the OPCS-4 coding system and a final report issued in April 1998, a further project was completed to look at the feasibility of basing future developments on clinical terms. The final report was produced in March 1999. The NHS Information Authority is currently in discussion with the Information Policy Unit on the need to take forward work on an OPCS-4 replacement. [Department of Health, 2000]

Each finished episode of care contains details of the patient's diagnoses, coded in up to seven diagnosis fields. The first of these fields codes for the primary diagnosis or the main condition treated or investigated during that episode. The remaining diagnosis fields record subsidiary diagnoses. Diagnosis codes commence with a letter and are followed by two or three digits. For example:

C67	Malignant neoplasm of bladder		
C670	Trigone of bladder	C675	Bladder neck
C671	Dome of bladder	C676	Ureteric orifice
C672	Lateral wall of bladder	C677	Urachus
C673	Anterior wall of bladder	C678	Overlapping lesion of bladder
C674	Posterior wall of bladder	C679	Bladder, unspecified

Up to four operative procedures may be coded within the HES database. Each of these operative procedure fields is associated with another field that records the date of the operative procedure. These tend to be recorded in date order and therefore the main surgery performed during an admission may not necessarily be recorded in the first operative procedure field. The OPCS-4 coding system consists of a tabular list of 23 anatomically based chapters, the majority relating to a whole or part of a body system. Each chapter is allocated an alphabetic character that forms the first digit of the code. Each chapter is then subdivided into separate organ sections. For example, chapter M refers to the urinary tract and this is subdivided into kidney, prostate, bladder etc. Within each of these subsections, operative procedures then tend to be sub-classified into groups labelled major, intermediate or minor. Finally, each categorisation usually includes sub-categories designated 'other specified' and 'unspecified'. For example:

M02 Total excision of kidney

M021	Nephrectomy and excision of perirenal tissue	M025	Nephrectomy nec*
M022	Nephroureterectomy nec*	M026	Excision of rejected transplant kidney
M023	Bilateral nephrectomy	M028	Other specified
M024	Excision of half of horseshoe kidney	M029	Unspecified

*nec not elsewhere classified

For the purposes of the OPCS-4 coding system, operative procedures are defined as procedures carried out on patients either firstly, for the prevention, diagnosis, care or relief of disease; secondly, for the correction of deformity or deficit, including those performed for cosmetic reasons; and thirdly, those procedures associated with pregnancy, childbirth or procreative management. These procedures are normally performed in an operating theatre, by a surgeon, using aseptic measures, and under anaesthesia or sedation. [Office of Population Censuses and Surveys, 1996]

HES data cannot reliably be used to identify the cause of death of a patient whilst in hospital because the diagnosis fields are used primarily to identify the reason for original admission to hospital. HES can only record whether a death occurred in hospital. Deaths that occur out of hospital cannot therefore be identified using the HES database. To attempt to rectify this, HES data have been linked to mortality data from the Office of National Statistics (ONS). The linked data file is available in a national linked file for the years 1998-2002 and is only available to defined users with the permission of the Patient Information Advisory Group of the Department of Health. [Patient Information Advisory Group, 2004; Department of Health, 2000]

3.3 Data quality

In general, the quality of any database depends on whether the data are complete, accurate and reliable – or in other words that the data measure what they were intended to measure. There are concerns with the quality of the data within the HES database. [Williams J et al, 2002] These are similar to concerns raised regarding any routinely collected database where data validation does not occur at source. [Bloor K et al, 2004] Many of the source systems of the different NHS providers submitting data to the HES allow the use of local or modified codes that are not nationally valid. Therefore, there is a requirement to crosscheck the consistency of coding between fields and to validate individual values in fields. Furthermore, the local data provider may alter local records after the HES record has been sent to the HES database. This can result in discrepancies between records held centrally and those on local systems.

A number of checks are applied to the HES data and these fall into the categories of verification, autocleaning and validation. For the record of a patient episode to be verified by HES, the record must contain details of an appropriate hospital provider, details of the type of admission and contain a date for the end of that episode which falls within the appropriate HES year. A record will be rejected if these data characteristics are not detected. The rejected records can then be returned to the data provider in order that the errors may be rectified. [Department of Health, 2000]

Autocleaning refers to the process where certain data fields are analysed to see whether they make sense both in isolation and also with reference to other fields. Fields that are obviously incorrect are overwritten by deriving the correct value from other data fields. If this is not possible these fields are overwritten as 'unknown'. Specific fields, such as those referring to the duration of an episode can be calculated from the admission and discharge dates and these are automatically calculated. [Department of Health, 2000]

Validation refers to the process whereby individual episode records are tested against a set of rules with the aim of identifying errors that remain following the autocleaning process, but which cannot be corrected. Following this a report is generated that summarises the quality of the submission from the data provider. This report contains a target data quality threshold, expressed as a percentage, and this threshold acts as a benchmark against which data providers can assess their performance.

The HES database also assesses the extent to which it records all finished consultant episodes by comparing these against the Korner aggregate return. This is an independent process to that of HES and provides annual totals of finished consultant episodes. [Department of Health, 2000] The Healthcare Commission in England and the National Centre for Health Outcomes Development also produce regular publications on data quality within HES.

Studies examining the accuracy of diagnostic or procedural coding within routine healthcare statistics in the UK tend to be small and of variable quality. [Campbell S et al, 2001] A recent systematic review designed to identify published studies investigating the accuracy of routinely collected hospital episode data (defined as the proportion of hospital episode records that have the same code as that assigned by an independent review of the discharge summary), reported that the median overall accuracy rates for the HES database relating to diagnostic and procedural codes was 90%, but this dropped to a median of 70% when procedural codes alone were considered. [Campbell S et al, 2001] Accuracy rates for procedural coding were found to be higher in Scotland than in the rest of the UK (median 98%), but diagnostic coding rates were found to be similar in Scotland compared to elsewhere in the UK (median 89% versus median 90%). This study also found that the accuracy of coding varies according to the version of the ICD coding system used in the study.

The accuracy of coding within HES appears to have improved over the last decade. [Hansell A et al, 2001] For example, a study examining the accuracy of coding for varicose vein operations in one English region found that compared to local audit data, the coding accuracy was 45% in 1989 compared to 98% in1995. [Galland R et al, 2000] A further study reported that HES captured 99% of 30-day post-operative deaths occurring in-hospital, but this fell to 92% if deaths occurring outside of hospital were included. [Aylin P et al, 2001] The Kennedy report concluded that the HES database was sufficiently accurate to perform national comparisons. [Learning form Bristol, 2001;

Bottle A et al, 2002; Aylin P et al, 2004] The extent of coding within UK databases tends to be lower than in those from the US, but it is well recognised that there is a financial incentive in the US for more complete recording of data. [McKee M, 1993; Simborg D, 1981] Nevertheless, the true data quality within HES is not known: although coverage and completeness within HES are high, more recent studies would suggest that the data quality is variable. [Lakhani A, 2003]

The training of coding staff is clearly important if the quality of clinical coding is to improve. Telephone help-lines have been established for coding queries and additional information is available from the internet. [Harley K et al, 1996] Training courses are also available in order to both train and keep staff up to date. It is also planned to increase the resources for training additional clinical coders and to increase propagation of 'good practice' such as the presence of coders at multidisciplinary team meetings and coding on the basis of case notes rather than on the basis of discharge abstracts.

The involvement of clinicians in the process of coding is known to improve accuracy. [Yeoh C et al, 1993; Barrie J et al, 1992, Cleary R et al, 1994] Although a recent study did indicate that coders were more accurate than surgeons at assigning codes to operative notes and that the accuracy of coding increased when the operative note was type-written compared to when it was hand-written. [Arthur J et al, 2004] Other studies have also demonstrated that coding accuracy by trained coders is high. [Audit Commission, 1996; Walshe K et al, 1993] These studies, and others, demonstrate the need for clinicians to have a responsibility for coding. The planned use of routine data in monitoring performance following recommendations in the Kennedy report, together with the public availability of consultant level data will act as incentives for this to occur. [Bloor K et al, 2004; Williams J, 2001; Learning form Bristol, 2001] Given the paucity of studies over recent years examining the validity of data within HES, further studies are required to remedy this and to study reasons for allocation of differing codes to the same episodes of care between coders.

The data extracted from the HES database and used in this thesis cover the years 1995/1996 to 2001/2002 and contain records of all admissions during which one of three urological cancer procedures took place – radical prostatectomy, radical cystectomy and radical nephrectomy. Moreover, the extract also contains from 1998/1999 all admissions in the year prior to (to capture comorbidity) as well as in the year subsequent to the surgical procedure (to capture readmissions). A unique encrypted patient identifier based either on NHS number or date of birth, sex and postcode was used to allow linkage of records within the HES database.

Chapter 4

Validity of ICD-10 administrative data to assess comorbidity in patients undergoing radical urological cancer surgery in England

4.1 Objectives

To evaluate the validity of the Charlson comorbidity score based on ICD-10 codes in patients undergoing urological cancer surgery within an English administrative database.

4.2 Introduction

Case-mix adjustment forms an essential component of any study evaluating outcomes of care using administrative data, as differences in baseline patient characteristics may account for many of the observed differences in outcomes.[Park R et al, 1990; Elixhauser A et al, 1998] These characteristics include demographic features such as patient age, sex and socioeconomic status, but also include differences in both the presence and severity of comorbid disease and the severity of the primary disease for which medical and surgical treatment is taking place. However, practical constraints often limit the extent of case-mix adjustment within administrative databases. [Iezzoni L, 1997; Finlayson E et al, 2002; Iezonni L, 1990; Blumberg M, 1986]

Comorbid disease may be defined as pre-existing disease or illness that affects a patient in addition to but not as a result of a primary diagnosis. [Elixhauser A et al, 1998] In an attempt to adjust for the presence or absence of comorbid disease several comorbidity scoring systems have been previously developed. [Ghali W et al, 1996] One of the most widely used and validated systems, developed by Charlson et al in 1987, was developed to predict one-year survival in a cohort of medical in-patients and then validated on a population of patients undergoing surgery for breast cancer. [Charlson M et al, 1987; Elixhauser A et al, 1998] This scoring system was subsequently adapted for use with administrative databases using diagnostic codes from the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) by Deyo et al and then further adapted by a collaboration of workers at Dartmouth and Manitoba Universities. [Department of Health and Human Services, 1998; World Health Organisation, 1997; Romano P et al, 1993; Romano P et al, 1993; Deyo R et al, 1992] The Charlson Index consists of 19 different disease comorbidity categories each allocated a weight of 1 to 6 based on the adjusted relative risk of one-year mortality and summed to provide a total score. [Charlson M et al, 1987] A number of previous studies using administrative data to examine outcomes following surgery have derived a Charlson score not only from records of the hospital admission in which surgery took place but also considered records of admissions preceding the admission for surgery in an attempt to capture more complete comorbidity data. [Birkmeyer J et al, 2003; Hu J et al, 2003]

The Hospital Episode Statistics (HES) database of the Department of Health in England records medical, demographic and administrative data relating to all in-patient admissions to hospitals in England. [Department of Health, 2001; Rowe R et al, 1972] Until 2002, the HES database contained seven diagnosis fields containing information relating to a patient's medical condition. The codes used to describe these diagnosis fields are defined from the tenth revision of the International Classification of Diseases (ICD-10). [World Health Organisation, 1994] The database also contains four operative procedure fields using codes defined from the Tabular List of the Classification of Surgical Operations and Procedures version 4 of the Offices of Populations, Censuses and Surveys (OPCS-4). [Offices of Populations Censuses and Surveys, 1997] The number of diagnosis and procedure fields increased to 14 and 12, respectively, after 2002.

In this study, the Deyo and Dartmouth-Manitoba ICD-9-CM adaptations of the Charlson score are translated for use with ICD-10 administrative databases, such as the English HES database (figure 4.1). For a comorbidity index to be clinically valid, it would be expected that increasing comorbidity scores would be related to risk factors associated with increasing comorbidity as well as to clinical outcomes. The objective of this study was therefore to test the validity of the translated Charlson scores within the English HES database on a cohort of patients undergoing radical urological cancer surgery based on these expectations. Data from both the index surgical admission and also from admissions over the year preceding surgery were used. Although previous groups have adapted the Deyo version of the Charlson score for use with ICD-10 data, to the best of our knowledge this is the first time that in addition the validity of the Dartmouth-Manitoba version of the Charlson score has been evaluated for ICD-10 administrative data. [Halfon P et al, 2002; Sundararajan V et al, 2004] This has considerable practical significance given the anticipated implementation of the ICD-10-CM coding system within the US.

4.3 Methods

Data

For this chapter of the thesis, patients undergoing radical prostatectomy (RP), radical cystectomy (RC) or radical nephrectomy (RN) – as defined in Chapter 5 – were included if their surgery occurred between the data years 1998/1999 to 2001/2002 as the HES identification number was only available for years subsequent to and including 1997/1998. On this basis, 20138 patients were included. Length of stay and in-hospital mortality, available in the HES database, were used as clinical outcomes. However, the use of length of stay as a measure of outcome is in part limited, as it may be subject to variations in local norms, practices and protocols.

Admissions in the year before surgery

All admissions recorded over a period of one year prior to the date of the index admission for surgery were acquired from the HES database through a process of internal data linkage using the HES identification number, which uniquely identifies a patient across all years of the database. Using the index episode alone is known to limit comorbidity detection as the diagnosis fields can become 'overcrowded' with complications of care occurring within the index episode. [Finlayson E et al, 2002; Jencks S et al, 1988; Iezonni L et al, 19924; Ghali W et al, 2001] For this reason preceding admissions were examined in order to maximise the detection of comorbid disease and this approach is similar to that used in previous studies performed in the US using ICD-9-CM codes. [Finlayson E et al, 2002; Hu J et al 2003; Birkmeyer J et al, 2002; Cleves M et al, 1997; Begg C et al, 1998]

ICD Translation

The ICD-9-CM codes defining the 17 comorbidity categories of the Deyo and Dartmouth-Manitoba adaptations of the original 19 Charlson comorbidity categories were converted to ICD-10 codes using the World Health Organisation ICD-9 to ICD-10 translator (Appendix 2). [World Health Organisation, 1997] A small number of the Deyo and Dartmouth-Manitoba codes represented procedures rather than diagnoses and these were directly translated into OPCS-4 codes. In addition, a very small number (13) of the codes generated by the translator failed to make clinical sense within their diagnostic categories and were therefore corrected (see Appendix 2).

Defining comorbid disease and statistical analysis

A comorbid disease was defined as present if an ICD-10 or OPCS-4 code translation of the Deyo and Dartmouth-Manitoba ICD-9-CM codes was present in any of the seven diagnosis fields or any of the four operative procedure fields, respectively of either the index episode or the previous admissions over the year before surgery (see Appendix 2). [Deyo R et al, 1992; Romano P et al, 1993] Codes that reflected the disease undergoing treatment were excluded from analysis. (For example, for patients undergoing RP, codes defining prostate cancer or radical prostatectomy were excluded from the comorbid disease category of malignancy.)

The prevalence associated with each comorbid disease category identified through the ICD-10/OPCS-4 translations of the Deyo and Dartmouth-Manitoba schemes was determined and the unweighted kappa statistic calculated to determine the degree of agreement between the two methods. [Sackett D, 1991; Ghali W et al, 1996; Fleiss J et al, 2003] Charlson scores were then calculated for each of the two new adaptations, using Charlson's original weights (table 4.2). [Charlson M et al, 1987] Associations between the new Charlson scores and risk factors associated with increasing comorbidity (patient age, sex, and method of hospital admission), and the extent to which the Charlson scores could be used to predict clinical outcomes (in-hospital mortality and length of stay) were determined. [Ghali W et al, 1996; Deyo R et al, 1992; Romano P et al, 1993] Chi-squared statistics and t-tests were used to examine relationships between the presence or absence of comorbidity on the one hand, and age, sex, method of admission (emergency vs. planned), in-hospital mortality, and length of hospital stay on the other.

The c-statistic, reporting the area under the receiver-operating curve, was used to assess the discriminative ability of logistic models to predict in-hospital mortality. [Hosmer D et al, 2000] The likelihood ratio test was used to assess whether the addition of either Charlson score to logistic models containing age and sex alone resulted in significant improvement in model fit. All p-values are two-sided and a p-value of <0.05 was defined as significant. All data analysis was performed using Stata Statistical software version 8.0.

4.5 Results

Demographic characteristics, method of admission, length of hospital stay, in-hospital mortality rates, and the number of days spent in hospital over the year prior to surgery are presented in table 4.1 for each of the three cohorts of patients.

Table 4.2 demonstrates the prevalence of each of the 17 comorbid disease categories using the ICD-10/OPCS-4 translations of the Deyo and Dartmouth-Manitoba ICD-9-CM codes. The observed disagreement between the two methods of coding for each comorbidity varied from 0.0% to 9.4%. Agreement was greater than 98% for all except three comorbidities. Low kappas were observed for the comorbid disease categories of mild (k=0.56) and severe (k=0.28) liver disease, and hemiplegia/paraplegia (k=0.64), but the prevalence of these conditions was very low. However, low kappas were also found for the peripheral vascular disease (k=0.56), malignancy (k=0.37) and metastatic solid tumour (k=0.50) categories that have a relatively high prevalence. These low kappa statistics are predominantly explained by differences between the Deyo and Dartmouth-Manitoba adaptations in either coding philosophy or inclusion of admissions preceding surgery (Appendix 2, p241-242).

Charlson scores derived by the two differing coding schemes were identical in 16667 cases (82.8%). The Charlson score derived by the Dartmouth-Manitoba method was higher in 14.4% of cases and that derived by the Deyo method was higher in 2.7% of cases. Agreement between the two methods was moderate (unweighted kappa=0.63). Over half of the total number of patients had a Charlson score of zero, which indicates that they did not have comorbidity according to either version. Charlson scores on average were lower for RP than for RC or RN (table 4.3). For example almost 90% of patients undergoing RP did not have any comorbidity compared to between about half to three-quarters of patients for RC and RN.

Associations between the presence or absence of comorbid disease on the one hand and risk factors for comorbidity and outcomes on the other are presented in table 4.4. Patients with comorbidity (Charlson score ≥1) were older than patients without comorbidity using either the Charlson Deyo or Dartmouth-Manitoba method. The proportion of patients who were men tended to be higher in those with comorbidity compared to without. With the exception of patients undergoing RP, patients with comorbid disease were also more likely to be admitted to hospital as an emergency than patients without comorbid disease.

Both translations of the Charlson score were predictors of in-hospital mortality, with the exception of patients undergoing RP (table 4.4). For example, using the Charlson Dartmouth-Manitoba score, the average in-hospital mortality rate for patients with comorbidity undergoing RN was 3.6% and was 1.1% for those without comorbidity. Similarly, length of stay was longer in patients with comorbidity compared to those without, except for those undergoing RC. For instance, patients with comorbidity undergoing RP and RN tended to stay approximately 1 and 2 days longer in hospital, respectively, than patients without comorbidity (table 4.4).

In a similar fashion to previous US studies, the c-statistic indicating the discriminative power of multivariate logistic models to predict in-hospital mortality was also calculated (table 4.5). [Ghali W et al, 1996; Cleves M et al, 1997] Models considering all patients and containing the covariates age and sex alone had moderate discriminative ability (c-statistic=0.69). Addition of either Charlson score to these models tended to make only modest further improvement, and the magnitude of this effect was dependent on the surgical procedure. C-statistics for models containing age, sex and either Charlson Deyo or Dartmouth-Manitoba score were very similar (table 4.5).

Based on the likelihood ratio test and considering all patients in the study, the addition of either Charlson score to models containing age and sex alone resulted in significant improvement to the models ($p<0.001$). However, when considering only patients undergoing RP, addition of the Charlson Dartmouth-Manitoba score to the age and sex model failed to make any significant improvement and addition of the Charlson Deyo score reached only borderline significance (table 4.5). For RC and RN, addition of either Charlson score to age and sex resulted in significantly better model fit, although the impact was greatest for RN.

Although inclusion of the Charlson Deyo score resulted in significantly better model fit for RP ($p=0.048$), the c-statistic fell when this score was added to the model containing age and sex alone (c=0.69 and 0.72, respectively). These apparently inconsistent findings are possible given that the c-statistic and the likelihood ratio test measure different aspects of model performance.

4.5 Discussion

The Deyo and Dartmouth-Manitoba ICD-9-CM adaptations of the Charlson score were translated into ICD-10 codes and subsequently applied to a cohort of patients undergoing radical urological cancer surgery within a large English administrative database. The obtained Charlson scores were higher in older patients, in men, and in those admitted to hospital as an emergency, and were also significant predictors of short-term outcome. Addition of either Charlson score to models predicting in-hospital mortality that already contained the covariates age and sex resulted in significantly better model fit but at best only small improvement in predictive power. Both Charlson scores performed similarly in models predicting in-hospital mortality, despite slight differences in coding philosophy.

There is general agreement regarding the need to measure comorbidity within studies comparing surgical outcomes between different treatment modalities or providers in order to attempt to remove one factor that may explain observed differences in outcomes. However, there is poor consensus about how this should be achieved. [Iezonni L, 1997; Fisher E et al, 1992] Furthermore, developing and then validating a novel risk-adjuster is both expensive and time-consuming. [Rosenthal G et al, 1994] The use of previously developed and validated risk adjustors, despite their limitations, is therefore attractive. Although the process of risk adjustment can never be complete, a degree of risk adjustment is considered necessary to avoid penalising hospitals or surgeons treating the highest risk or most complex patients, and for data to be taken credibly by physicians. [Schneider E et al, 1996; Iezonni L, 1999]

Validity of the translated Charlson scores

Increasing Charlson scores were associated with risk factors for increasing comorbidity and with clinical outcomes. However, when considering the subgroup of patients undergoing RP, there did not appear to be an association between comorbidity and in-hospital mortality. This was not surprising given the difficulty in accurately interpreting mortality rates following RP because of the very low numbers involved. Given that RP tends to be offered only to patients judged to have a life expectancy of at least ten years, patients undergoing RP tend to be younger and healthier than those undergoing RC or RN. [Singh R et al, 2004] This also explains why the Charlson scores were lowest for those undergoing RP.

When considering all patients, those with comorbidity had a longer length of stay than those without. However, there was no apparent relationship between comorbidity and length of stay within the subgroup of patients undergoing RC. A possible explanation for this may be that length of stay depends strongly on the severity of the underlying procedure. It is generally accepted that RC has the greatest physiological impact compared to RP or RN and as such the severity of the operation itself may have a greater influence on length of stay than the degree of comorbidity (see chapter 8).

Comparison with previous studies

The Deyo and Dartmouth-Manitoba Charlson scores generated in this study agreed in 83% of cases (k=0.63). This compares with a previous US study of patients identified from an ICD-9-CM database undergoing coronary artery bypass surgery that found the agreement to be 90%. [Ghali W et al, 1996] This difference might be explained by the presence of a different prevalence of comorbidity between these patient populations. It might also be explained by differences between the ICD-9-CM and ICD-10 coding systems and inaccuracies inherent within the translating system that was used to perform the code translation. [McKee M et al, 1997]

The Charlson scores derived from this UK study tended to be lower than those derived in previous studies using the US Medicare database (and therefore only containing patients aged over 65 years). The proportion of patients undergoing RP aged over 65 years in the present study with a Charlson Dartmouth-Manitoba score of ≥3 was 1.7%, compared to 7.6% in a US study. [Hu J et al, 2003] In contrast, another US study of RP reported that only about 3.5% of patients had a Charlson Dartmouth-Manitoba score ≥2, compared to 5.6% in this English study. [Begg C et al, 1998] For RC, the proportion of patients in this study aged over 65 years with a Charlson score ≥3 was 15.9% for the Dartmouth-Manitoba adaptation. In a US study the corresponding proportion was 36.6%. [Birkmeyer J et al, 2003] There are several reasons that may explain the generally lower levels of comorbidity derived from the HES database compared with these other studies. Firstly, the number of diagnosis fields within the HES database is limited and as a consequence some diagnoses may be omitted. This has been recognised and the number of diagnosis fields increased to 14 in 2002. [McKee M et al, 1997] Secondly, the association between coding and reimbursement in the US offers financial incentives for more complete and extensive diagnostic coding compared to healthcare systems where this is not the case. [McKee M et al, 1999; Hsia D et al, 1998] Thirdly, patients in the UK undergoing radical urological cancer surgery may actually have less comorbid disease than those in the US, possibly based on more restrictive patient selection for surgical treatment. Although of these three reasons, the last is unlikely.

There are few studies that accurately portray the prevalence of comorbid disease in patients undergoing radical urological cancer surgery in England. However, a retrospective case note study of 96 patients with a mean age of 66 years who underwent RC in one English region reported the percentage of patients with the following comorbid conditions (proportions of the equivalent Deyo and Dartmouth-Manitoba translations from the present study are given in parentheses, respectively) as: myocardial infarction 2.0% (2.1%, 2.1%); diabetes mellitus 7.3% (5.5%, 5.4%); respiratory disease 10.4% (5.3%, 5.2%); renal failure 5.2% (2.1%, 2.3%); neurological disease 2.0% (1.4%, 1,5%). [Chahal R et al, 2003] These figures indicate that the present study based on administrative data tended to detect a lower proportion of comorbid disease for most, but not all, disease categories than the study based on case note data. Discrepancies seem to be most marked for disease categories where the clinical diagnosis is not clear cut and consequently more subject to coding variation and more likely to be inconsistent between hospitals. For example, it is more difficult to define and therefore code respiratory or renal disease compared to myocardial infarction and diabetes mellitus.

C-statistics derived from models predicting in-hospital mortality in this English study and containing the covariates age, sex, and either Charlson Deyo or Dartmouth-Manitoba score (0.71 and 0.73, respectively) were very similar to those from previous US studies. [Cleves M et al, 1997; Ghali W et al, 1996] A study of surgical patients in a single US state reported c-statistics of 0.71 and 0.69 for models predicting 30-day mortality containing Charlson Deyo and Dartmouth-Manitoba scores in addition to age and sex, respectively and 0.64 for a model containing age and sex alone. [Cleves M et al, 1997] Another study of 13,117 coronary artery bypass surgery patients in another state reported a c-statistic of 0.66 for a model predicting in-hospital mortality containing age and sex alone, and 0.70 for a model that additionally contained the Charlson Deyo score. [Ghali W et al, 1996]

All this suggests that firstly Charlson scores derived from ICD-10 administrative data perform similarly to those derived from ICD-9 data in models predicting mortality. Secondly, adjusting for comorbidity in studies using administrative data, either based on ICD-9 or ICD-10 codes, does not seem to provide a large improvement over and above adjusting for age and sex alone.

Two previous studies have translated the Deyo version of the Charlson score for use with ICD-10 data. [Halfon P et al, 2002; Sundararajan V et al, 2004] The first was carried out in Switzerland and did not explicitly state how the translation from ICD-9 to ICD-10 was performed. [Halfon P et al, 2002] The ICD-10 translation was validated in 3474 patients admitted to a Swiss hospital. It was found that patients with a Charlson score of 3 or higher had a 2.2 times higher readmission rate than those with a score of less than 3. Data from preceding admissions were not used to identify the presence of comorbid disease. The second study translated the Australian ICD-9 version using a "mapping algorithm" and expert opinion. [Sundararajan V et al, 2004] It was validated using data, from the State of Victoria, Australia, of all multiday hospital admissions from 1998 to 2002. It was found that the prevalence of comorbidity over this period based on the ICD-10 translation was similar to the prevalence in the two immediately preceding years based on the ICD-9. Furthermore, there was a strong association between the Charlson score based on the ICD-10 and in-hospital mortality.

A comparison of the current translation with these Swiss and Australian translations revealed many broad areas of overlap, but also for some disease categories marked discrepancies. There was no consistent pattern to these discrepancies. An evaluation was therefore performed of how well the Charlson comorbidity scores derived from these Swiss and Australian translations could predict in-hospital mortality in this HES dataset. The c-statistic for the Australian study was 0.71 and for the Swiss study 0.72, which are remarkably similar to the result of 0.71 derived from the current data. All of this suggests that the discrepancies between the 3 translations had little impact on the predictive validity. Despite this further work is needed to develop consensus on the ICD-10 version of the Charlson comorbidity score.

Study limitations

There are a number of potential limitations associated with this study. First, administrative data tend not to provide as complete or accurate an identification of the presence of comorbid disease compared to studies based on clinical databases. [Powell H et al, 2001] The magnitude of this effect varies according to the type of comorbidity. [Quan H et al, 2002; Humphries K et al, 2000] Furthermore, it has been argued that most administrative databases have been incompletely validated on the scale necessary to develop a comorbidity index for widespread use. [Campbell S et al, 2001; Orchard C et al, 1996; Mukherjee A et al, 1991] Nevertheless, despite these limitations several studies from different countries have demonstrated that administrative data can identify the presence of comorbid disease to partly control for differences in case-mix between patient populations. [Malenka D et al, 1994; Quan H et al, 2002; Humphries K et al, 2000]

Second, as the timing of a diagnosis or an intervention within an admission is often not recorded, it can be difficult to distinguish between a comorbidity and a complication of care. [Hughes J et al, 1996; Iezzoni L et al, 1992; Ghali W et al, 2001] Approximately one third of patients with renal disease in the present study (using the Dartmouth-Manitoba translation) were coded from the index admission alone, which could in theory represent complications rather than pre-existing diagnoses. Third, the dichotomous nature of most comorbidity codes in administrative databases fails to reflect disease severity. Fourth, coding practice can vary both over time and between hospitals. This can limit the generalisability of results and create inconsistencies in comparing results over time and between geographical locations. [Cleves M et al, 1997; Iezonni L, 1993; McKee M et al, 1999; Chenet L et al, !996] There may be hospitals that are persistent poor performers in recording diagnosis codes. It has been suggested that teams of travelling coders should be established to diminish variation in coding practice both between hospitals and countries. Last, the original Charlson weights were derived from a sample of medical in-patients at a single New York hospital and these weights might not apply to the patients in this English study or to those patients in studies evaluating other translations. These limitations hamper the development of more sophisticated methods of comorbidity adjustment on the basis of administrative data.

4.6 Conclusions

Charlson scores derived from ICD-10 administrative data were higher in older patients, in men, and in those admitted to hospital as an emergency, and were also significant predictors of short-term outcome. Charlson Deyo and Dartmouth-Manitoba scores performed very similarly in risk models predicting hospital mortality following urological cancer surgery. Both scores can continue to be used to adjust for comorbidity following the anticipated implementation of the ICD-10 coding system in the US. However, adjusting for comorbidity does not seem to have a large additional impact when compared to adjusting for age and sex alone.

4.7 Tables and Figures

Figure 4.1: Schematic diagram demonstrating the relationship between previous adaptations of Charlson's original comorbidities and further translation for use with ICD-10 databases

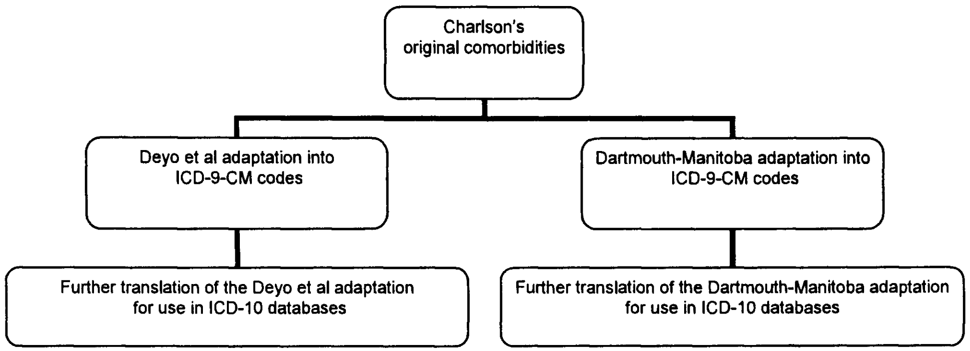


Table 4.1: Demographic characteristics and short-term outcomes of patients undergoing radical prostatectomy, radical cystectomy and radical nephrectomy in England between 1998 and 2001

Characteristic	All patients	Radical Prostatectomy	Radical Cystectomy	Radical Nephrectomy
Number of patients	20138	4786	4971	10381
Mean age in years (SD)	64.3 (10.3)	62.6 (5.8)	66.5 (9.2)	64.0 (12.1)
Men, number (%)	15098 (75.1)	4786 (100.0)	3770 (75.8)	6566 (63.3)
Race, number (%) white	13116 (95.7)	2998 (92.7)	3535 (97.4)	6597 (96.1)
Emergency admission, number (%)	1273 (6.3)	24 (0.5)	278 (5.6)	973 (9.4)
In-hospital mortality, number (%)	421 (2.1)	6 (0.1)	207 (4.2)	210 (2.0)
Mean length of stay (SD)	12.2 (10.5)	7.9 (5.0)	18.8 (14.0)	11.0 (8.9)
Mean hospital days in year prior to surgery (SD)	8.9 (15.0)	2.2 (4.9)	11.9 (15.5)	9.3 (16.3)

Table 4.2: Prevalence of comorbid conditions according to ICD-10 adaptations of the Deyo and Dartmouth-Manitoba coding schemes in 20138 patients undergoing radical urological cancer surgery in England 1998-2002

Comorbidity	Deyo ICD-10 Adaptation, number (%)	Dartmouth-Manitoba ICD-10 Adaptation, number (%)	Observed disagreement between the adaptations, number (%)	k statistic*	Charlson weight
Myocardial infarction	427 (2.1)	427 (2.1)	0 (0.0)	1.00	1
Congestive cardiac failure	48 (0.3)	58 (0.3)	10 (0.0)	0.91	1
Peripheral vascular disease	564 (2.8)	365 (1.8)	403 (2.0)	0.56	1
Cerebrovascular disease	172 (0.9)	161 (0.8)	31 (0.2)	0.91	1
Dementia	33 (0.2)	33 (0.2)	0 (0.0)	1.00	1
Chronic pulmonary disease	1062 (5.3)	1049 (5.2)	27 (0.1)	0.99	1
Rheumatological disease	283 (1.4)	252 (1.3)	41 (0.2)	0.92	1
Peptic ulcer disease	223 (1.1)	209 (1.0)	16 (0.1)	0.96	1
Mild liver disease	27 (0.1)	58 (0.3)	37 (0.2)	0.56	1
Diabetes (mild to moderate)	1078 (5.4)	1047 (5.2)	31 (0.2)	0.99	1
Diabetes with chronic complications	31 (0.2)	50 (0.2)	19 (0.1)	0.77	2
Hemiplegia or paraplegia	81 (0.4)	102 (0.5)	65 (0.3)	0.64	2
Renal disease	430 (2.1)	460 (2.3)	98 (0.5)	0.89	2
Any malignancy including lymphoma and leukaemia	751 (3.7)	2426 (12.0)	1889 (9.4)	0.37	2
Moderate or severe liver disease	115 (0.6)	21 (0.1)	98 (0.5)	0.28	3
Metastatic solid tumour	497 (2.5)	1410 (7.0)	917 (4.6)	0.50	6
AIDS	1 (0.0)	1 (0.0)	0 (0.0)	1.00	6

*kappa statistic representing the degree of agreement between the comorbidities generated by the Deyo and Dartmouth-Manitoba translations

Table 4.3: Charlson scores by procedure derived from using the ICD-10 Deyo and Dartmouth-Manitoba adaptations for patients undergoing radical urological cancer surgery in England between 1998-2002

Charlson Score	RP (Deyo) Number (%)	RP (Dartmouth-Manitoba) Number (%)	RC (Deyo) Number (%)	RC (Dartmouth-Manitoba) Number (%)	RN (Deyo) Number (%)	RN (Dartmouth-Manitoba) Number (%)
0	4285 (89.5)	4184 (87.4)	3724 (74.9)	2736 (55.0)	7523 (72.5)	6638 (63.9)
1	405 (8.5)	358 (7.5)	639 (12.9)	428 (8.6)	1365 (13.2)	1191 (11.5)
2	74 (1.5)	159 (3.3)	352 (6.5)	1045 (21.0)	757 (7.3)	1203 (11.6)
≥3	22 (0.5)	85(1.8)	283 (5.7)	762 (15.3)	736 (7.1)	1349 (13.0)

Table 4.4: Associations of ICD-10 derived Charlson scores with risk factors for comorbidity and clinical outcomes

	Charlson score					
	Deyo 0	Deyo ≥1	P value	*DM 0	*DM ≥1	P value
Radical prostatectomy						
Number of patients, (%)	4285 (89.5)	501 (10.5)	-	4184 (87.4)	602 (12.6)	-
Mean age (SD)	62.5 (5.8)	63.5 (5.8)	<0.001	62.5 (5.8)	63.3 (5.8)	0.002
Emergency admission, N (%)	18 (0.4)	6 (1.2)	0.020	21 (0.5)	3 (0.5)	0.990
In-hospital mortality, N (%)	5 (0.1)	1 (0.2)	0.620	4 (0.1)	2 (0.3)	0.125
Length of stay, mean (SD)	7.8 (4.8)	8.8 (6.1)	<0.001	7.8 (4.8)	8.6 (5.8)	<0.001
Radical cystectomy						
Number of patients, (%)	3724 (74.9)	1247 (25.1)	-	2736 (55.0)	2235 (44.0)	-
Mean age (SD)	66.0 (9.3)	68.0 (8.6)	<0.001	65.7 (9.2)	67.4 (9.0)	<0.001
Male sex, N (%)	2766 (64.6)	1004 (80.5)	<0.001	2046 (74.8)	1724 (77.1)	0.054
Emergency admission, N (%)	181 (4.9)	97 (7.8)	<0.001	126 (4.6)	152 (6.8)	0.001
In-hospital mortality, N (%)	129 (3.5)	78 (6.3)	<0.001	88 (3.2)	119 (5.3)	<0.001
Length of stay, mean (SD)	18.9 (13.0)	18.4 (16.8)	0.243	18.8 (13.5)	18.7 (14.7)	0.828
Radical nephrectomy						
Number of patients, (%)	7523 (72.5)	2858 (27.5)	-	6638 (63.9)	3743 (36.1)	-
Mean age (SD)	63.0 (12.3)	66.8 (11.0)	<0.001	62.9 (12.3)	66.0 (11.4)	<0.001
Male sex, N (%)	4671 (62.1)	876 (66.3)	<0.001	4124 (62.1)	2442 (65.2)	0.002
Emergency admission, N (%)	633 (8.4)	340 (11.9)	<0.001	541 (8.2)	432 (11.5)	<0.001
In-hospital mortality, N (%)	107 (1.4)	103 (3.6)	<0.001	76 (1.1)	134 (3.6)	<0.001
Length of stay, mean (SD)	10.5 (7.5)	12.3 (11.5)	<0.001	10.2 (7.3)	12.4 (11.0)	<0.001

DM=Dartmouth-Manitoba

Table 4.5: C-statistics depicting the discriminative ability of models containing different covariates to predict in-hospital mortality

Patient category	Covariate			P value of adding Charlson Deyo score to models containing age and sex	P value of adding Charlson Dartmouth-Manitoba score to models containing age and sex
	Age and sex alone	Age, sex and Charlson Deyo score	Age, sex and Charlson Dartmouth-Manitoba score		
All patients	0.69	0.71	0.73	<0.001	<0.001
RP	0.72	0.69	0.72	0.048	0.056
RC	0.63	0.64	0.65	0.018	<0.001
RN	0.68	0.71	0.73	<0.001	<0.001

RP = Radical prostatectomy; RC = Radical cystectomy; RN = Radical nephrectomy

Section 3

Practice and Outcomes for radical urological cancer surgery in England based on HES data

Chapter 5

Practice and outcomes for radical urological cancer surgery in England: a descriptive analysis of the Hospital Episode Statistics dataset

5.1 Objectives

The objectives of this chapter are: first, to describe the process of data acquisition from the HES database and second, to describe temporal changes in patient characteristics and outcomes for radical prostatectomy, radical cystectomy and radical nephrectomy performed in England between 1995 and 2002 using the routinely collected HES dataset.

5.2 HES data acquisition

An application was made to the HES database in August 2002 at the beginning of this project to acquire a data extract of all patients recorded as having undergone a radical prostatectomy (RP), radical cystectomy (RC) or radical nephrectomy (RN) in England between the HES data years of 1995/1996 and 2001/2002 (see Appendix 3). Patients were included if firstly, an operative procedure code (OPCS-4) for any one of these procedures was present in any of the four operative procedure fields and secondly, a cancer diagnosis code for the corresponding cancer was present in any of the seven diagnosis fields (see sections 5.3.1, 5.4.1 and 5.5.1 for precise coding details of the filters used to select data relating to RP, RC and RN, respectively). [Office of Populations, Censuses and Surveys, 1996; World Health Organisation, 1994]

Only finished consultant episodes (FCE) were included within the data extract (see Chapter 3). Unfinished consultant episodes refer to episodes of care where the patient was still undergoing treatment on the last day of the HES year (31st March) and were excluded from the study. Records from unfinished consultant episodes do not contain clinical information, as clinical data are only recorded once an episode has been completed.

The HES database contains over 50 data fields, including details regarding operative procedures, medical diagnoses, location of treatment and patient demographic data. The fields selected for inclusion within the data extract are listed within the data application form in Appendix 3. In essence, the following types of data were obtained: demographic data, diagnostic data, procedural data and outcome data. In addition to the episodes in which surgery took place, we also requested data regarding all FCEs that occurred over a period of one year after and one year before the date of admission to hospital for surgery in order that data regarding comorbidity (see Chapter 4) and readmissions following surgery (see Chapter 6), respectively, could be analysed. These FCEs were identified through the use of the HESID number, which is a unique patient identifier within the HES database. This number was only available from years subsequent to and including the data year 1997/1998.

As this study did not include paediatric patients, all patients under the age of 17 years at the start of their index admission were excluded from any further analysis. Patients recorded as having undergone RP or RC were also excluded from the study if they were aged over 80 years, and patients undergoing RN were excluded if they were aged over 90 years as it was judged by the project advisory group that radical cancer procedures would be unlikely to be performed on patients in this age group and the chances of coding errors would therefore be higher. The data extract obtained from the above process was used in all analyses in this thesis (see chapters 4, 5, 6 and 9).

Determination of hospital procedural volumes

The annual hospital volume of each procedure was determined by counting the number of patients treated within each NHS Trust. The HES data field PRODMUT identifies the NHS Trust were treatment took place. The total number of organisations submitting data per year to the HES database is listed below. The trend over this time period was towards a gradual reduction in the number of separate organisations. Predominantly, this was due to merging of individual NHS trusts.

1995/1996	388	1999/2000	330
1996/1997	379	2000/2001	316
1997/1998	371	2001/2002	338
1998/1999	358		

Statistical analysis

In the HES database, waiting time duration is defined as the time in days from the date on which it was decided to admit the patient for surgery to the date of admission to hospital when surgery took place. Linear or logistic regression was used to examine changes in demographic characteristics and outcomes over time and also to examine changes in waiting time and patient outcomes according to patient demographics. All p-values are two-sided and a p-value of <0.05 was defined as significant. All data analyses were conducted using Stata Statistical Software version 8.0 (Statacorp, USA).

5.3 Radical Prostatectomy

5.3.1 Methods (Radical prostatectomy)

Data were extracted from the HES database for the data years 1995/1996 to 2001/2002 for all patients recorded as having undergone a radical prostatectomy (RP). Patients were included if an International Classification of Diseases code (ICD-10) for malignant neoplasm of the prostate (C61) was present in any of the seven diagnosis fields and an Office of Population Censuses and Surveys operative procedure code (OPCS-4) indicating total excision of prostate and capsule of prostate, perineal prostatectomy, other specified open excision of prostate or unspecified open excision of prostate was present in any one of the four operative procedure fields. Patients were excluded from the study if their age fell outside of the range 17-80 years and on this basis 26 patients were excluded. Overall 6166 patients were included.

5.3.2 Results (Radical prostatectomy)

Descriptive statistics of the entire cohort of 6166 patients are shown in table 5.1. Just over one-third of the patients undergoing RP (41.5%) were 65 years of age or older. There was a statistically significant increase in the number of RPs performed each year over the duration of the study from 284 in 1995/1996 to 1751 in 2000/2001 (table 5.2). As expected, the mean annual hospital volumes of RP also increased over the study duration. The proportion of patients admitted as an emergency over the duration of the study fell from 0.7% in 1995/1996 to 0.3% in 2001/2002, although this peaked at 1.7% in 1996/1997 (table 5.2). Patient age did not change appreciably over this time period.

There was a statistically significant increase over time in waiting time duration, from around 40 days in 1995/1996 to around 45 days in 2001/2002. Mean length of stay fell from 9.6 days to 7.2 days over the study period. In-hospital mortality rates also fell over this period, although the number of patients involved was very small (table 5.2).

There was a statistically significant increase in waiting time duration with age. For instance, patients aged over 75 years waited on average almost 8 days longer than patients aged under 55 years (table 5.3). Older patients also had a longer length of stay than younger patients. There was no appreciable difference in length of stay in those that had waited less than compared to greater than 4 weeks to be admitted for surgery. However, length of stay was significantly longer in those admitted as an emergency compared to in those who were admitted electively. However, the number of patients admitted as an emergency was very small, which is consistent with the fact that RP tends to be offered to younger and healthier patients than for RC and RN. In-hospital mortality increased with increasing patient age. In-hospital mortality was also higher in those admitted as an emergency compared to those admitted electively.

5.3.3 Discussion (Radical prostatectomy)

The annual number of RPs performed in England between 1995 and 2002 increased by over 500%. Average length of hospital stay and in-hospital mortality rates have decreased over this time period. Length of stay and in-hospital mortality rates were higher in older patients and in patients admitted as an emergency. There was no association between both length of stay and in-hospital mortality and the length of time spent waiting to be admitted for surgery.

Our finding of a large increase in the annual number of RPs has been previously documented in the UK and elsewhere. [Wilt T et al, 1999; Oliver S et al, 2003; Lu-Yao G et al, 1997] This increase in activity is due in part to the increased availability of prostate specific antigen testing (PSA) testing, but also to more widespread use of RP as a treatment for localised prostate cancer together with technical improvements to the operation (see chapter 2). [Donovan J et al, 1999] It could also be due to improvement in completeness and accuracy of coding over this time period, although given the magnitude of the increase in the numbers of RP and the observations of similar effects elsewhere, this explanation is unlikely to account for much of the observed increase.

This study was unable to include RPs carried out within the independent sector. Compared to other urological cancer procedures, a greater proportion of RPs are performed within the independent sector and this may be around 25% of the overall total, although exact figures are not available (see Chapter 8). [British Association of Urological Surgeons, 2002] More recent initiaves have also led to some NHS procedures being performed within the private sector, either at private hospitals or within Independent Sector Treatment Centres. The number of RPs included within this study is therefore an underestimation of the total number performed in England.

The age of the men in this study of RP is similar to those of previous studies. For example the mean age of 13398 men undergoing RP in a US study was 65 years, and was 62 years in single centre US study of 856 patients, compared to 62.6 years in this study. [Wilt T et al, 1999; Leibman B et al, 1998] In a similar fashion to the findings in this study, length of hospital stay has also fallen over time within the US. Two studies using Medicare data (and therefore only including patients over the age of 65 years) found that between 1991-1998 the mean length of stay decreased from 8.1 days to 5.1

days and between 1991-1994 length of stay fell from 9.0 days to 7.0 days. [Hu J et al, 2003b; Yao S-L et al, 1999] Although the length of hospital stay in our study fell from a mean of 9.6 days in 1995/1996 to a mean of 7.2 days in 2001/2002, the most recent figures are still considerably higher than those reported in many US studies. In the US, stays of 5-8 days have been reduced in some series to 1.3 days and some case series have even reported RPs performed as day cases. [Koch M et al, 1996; Licht M et al, 1994; Ramsden A et al, 2003; Kirsh E et al, 2000] There are several reasons for this discrepancy in length of stay between the US and the UK. First, it may in part reflect the differing reimbursement systems between the UK and the US. For example, a US study calculated that the average hospital charges for a patient undergoing RP whose length of stay was 5 days was $11,795 compared to $10,042 for patients staying 4 days. [Leibman B et al, 1998] This association between length of stay and hospital charges may create a drive to decrease length of stay and therefore lower hospital charges in the US. Second, it may reflect differing discharge policies and support facilities for post-operative care between the US and the UK or differences in anaesthetic practice. [Ramsden A et al, 2003] Last, it may also reflect differences in the severity of comorbid disease. However, it is unlikely that this explanation would substantially account for the differences in length of stay, given that RP tends to be performed on relatively healthy men with a life-expectancy of at least 10 years. [Singh R et al, 2004]

Waiting time increased over the last two years of this study. This could be due to a lack of capacity given the large increase in the numbers of RP over the latter period of the study. However, there did not appear to be any significant association between waiting time duration and either in-hospital mortality rates or length of hospital stay. This finding is not surprising given the relatively low physiological impact of RP and also the relatively prolonged natural history of prostate cancer compared to many other malignancies. However, it is important to note that the definition of waiting time within the HES database only measures the time from the decision to undergo surgery and does not include the difference between this and the time from initial diagnosis.

Mean annual hospital volume increased by approximately three-fold over the study period. This compares with an approximate six-fold increase in the total annual number of RPs performed in England over this period. The more limited increase in annual hospital volume may therefore in part be explained by the increase in the national trend, but also by the increased numbers of NHS Trusts that are performing this procedure. [Oliver SE et al, 2003] UK guidance to centralise RPs in regional cancer centres was issued in 2002 and recommended that RPs should only be performed by hospitals that care for a population of at least one million people. [National Institute of Clinical Excellence, 2002] As England has a population of approximately 50 million [National Statistics, 2004] and about 1750 RPs are carried out each year according to this study, the UK guidance implies that hospitals should perform at least 35 RPs per year. In 2001/2002, the mean annual hospital volume was 26, implying that many UK hospitals perform fewer RPs than currently recommended. In 2001/2002, 110 of the 117 NHS Trusts that carried out RPs in England did not meet this target on the basis of the HES data.

5.4 Radical Cystectomy

5.4.1 Methods (Radical cystectomy)

Data were extracted from the HES database for the data years 1995/1996 to 2001/2002 for all patients recorded as having undergone a radical cystectomy (RC). Patients were included in this study if firstly, an International Classification of Diseases code (ICD-10) for malignant neoplasm of the bladder was present in any of the seven diagnosis fields, and secondly, an Office of Population Censuses and Surveys operative procedure code (OPCS-4) indicating cystoprostatectomy, cystourethrectomy, cystectomy not elsewhere classified, simple cystectomy, or other specified total excision of bladder was present in any of the four operative procedure fields. Patients were excluded from the study if their age fell outside of the range 17-90 years (39 patients). Overall, 8228 patients were included.

5.4.2 Results (Radical Cystectomy)

Descriptive statistics of the entire cohort of 8228 patients are shown in table 5.4. Almost two-thirds of the patients undergoing RC were 65 years of age or older. Approximately three-quarters were men. There was an increase in the number of RCs performed over the duration of the study, from 1013 in 1995/1996 to 1256 in 2001/2002 (table 5.5). The proportion of patients admitted as an emergency seemed to have fallen over the duration of the study (table 5.5). The mean annual hospital volumes of RC increased over the study duration. There is some indication that waiting time duration decreased over time, but this effect was not statistically significant and the decrease was only about 1½ days over the entire study period. Patient age and the proportion of operations carried out in men did not change appreciably with time. Mean length of stay decreased from 20.7 days in 1995/1996 to 18.7 days in 2001/2002 (table 5.5). In-hospital mortality rates also fell over the study duration from 5.3% in 1995 to 3.6% in 2001.

There was a slight but statistically significant increase in waiting time duration with age. For example, patients less than 55 years waited 24.8 days for admission for surgery, compared to 27.9 days for patients aged over 80 years. Men waited longer than women. Older patients had a longer length of stay than younger patients (table 5.6). Men had a slightly shorter length of stay compared to women. Length of stay was almost identical for patients who had waited less than compared to greater than 4 weeks (table 5.6). Patients admitted as an emergency had a mean length of stay about 10 days longer than those admitted electively.

In-hospital mortality increased with age. In-hospital mortality was also slightly higher in women compared to men and in patients who had waited over 4 weeks for surgery compared to those who had waited less than 4 weeks for surgery (table 5.6). Patients admitted to hospital as an emergency had higher in-hospital mortality rates than those admitted electively. The length of stay in patients who died in hospital (mean 26.3, SE 0.29 days) was longer than in those who were discharged (mean 18.9, SE 0.14 days).

5.4.3 Discussion (Radical cystectomy)

The annual number of RCs performed in England between 1995 and 2002 has increased by approximately one quarter. Average length of stay and in-hospital mortality rates have decreased over this time period. Length of stay and in-hospital mortality were higher in older patients, in female patients, in those who had waited more than four weeks, and in those admitted as an emergency.

A number of the results from this study need to be explained in the light of methodological limitations associated with the use of administrative data sources such as the HES database. First, the observed increase in the number of patients undergoing RC over time might be explained partly by increased surgical activity or partly by improvements in the completeness and accuracy of coding. [Ballaro A et al, 2000; McKee M et al, 1997] On the basis of the current data, it is impossible to disentangle these effects. However, it is not likely that coding errors will play a major role in this study as RC and the diagnosis of bladder cancer represent key events that are easily definable and the study outcomes, length of stay and in-hospital mortality are not prone to interpretation. Second, although the observed in-hospital mortality decreased, the overall mortality might not have changed given the simultaneous fall in length of stay; with a shorter length of stay more patients might die after discharge. This possibility cannot be ignored as a study that combined HES data with mortality data in the former Oxford NHS health region showed an association between length of stay and in-hospital mortality rates. [Goldacre M et al, 2002; Jencks S et al, 1988; Henderson J et al, 1989; Gill L et al] Third, this study only included RCs carried out in NHS hospitals and not those in hospitals from the independent sector. Although exact figures are not available, the proportion of RCs performed in independent sector hospitals is likely to be less than 10% (see chapter 8). It is therefore unlikely that the major trends observed within NHS hospitals were influenced appreciably by changes in the independent sector. Despite these limitations, the consistency of the observed demographic trends over time within this study and the face validity of the observed associations between patient demographics and outcomes support the validity of these results.

Demographic characteristics of the patients included within this study are similar to those included in previous studies carried out in the UK and the US, although the observed mortality rates in this study are higher. [Finlayson E et al, 2003; Birkmeyer J et al, 2002; Rosario D et al, 2000; Chang S et al, 2002; Figueroa A et al, 1998] Nationwide US studies reported a 3.1% in-hospital mortality rate after 4937 RCs between 1995-1997 and a 4.0% in-hospital mortality rate after 22,349 RCs between 1994-1999. [Finlayson E et al, 2003; Birkmeyer J et al, 2002] The overall mortality rate in the 8228 patients in this study who underwent a RC between 1995-2002 was 4.5%. However, it is difficult to interpret the differences between these US and UK results without further details regarding disease severity, comorbidity, and discharge policies.

The mortality results reported in some single centre studies are considerably better than those observed in these nationwide results for England. For example, a single centre in the UK reported an overall mortality rate of 1.9% (CI: 0.3-7.7%) in 101 patients undergoing RC between 1992-1997. [Rosario D et al, 2000] Two US single centres reported perioperative mortality rates of 0.3% (CI: 0.02-2.11%) in 304 patients undergoing RC between1995-2000, [Chang S et al, 2002] and approximately 2.2% in 1166 patients undergoing RC over a 25-year period (1971-1996). [Figueroa A et al, 1998] These results demonstrate the low mortality rates that some centres have achieved, but it is uncertain how generalisable these results are given the potential of publication bias, the wide confidence intervals around these figures and other confounding factors. [Singh R et al, 2003]

Mean annual hospital volume increased by about 25% over the study duration. A similar proportional increase was observed in the total number of RCs carried out in England. This suggests that the increase in hospital volume can be explained by the national trend. This can be understood as UK guidance to centralise RCs in regional cancer centres was issued in 2002, and therefore does not affect the results of this study. [National Institute of Clinical Excellence, 2002] In the last year of the present study about 1250 RCs were performed and the mean annual hospital volume was 13. England has a population of approximately 50 million [National Statistics, 2004], so the average catchment population per hospital that performed RCs in 2001/2002 was about 500 000. This is lower than the recently updated UK recommended minimum catchment population of one million for teams delivering specialist urological cancer care. [National Institute of Clinical Excellence, 2002]

5.5 Radical Nephrectomy

5.5.1 Methods (Radical nephrectomy)

Data were similarly extracted from the HES database for the data years 1995/1996 to 2001/2002 for all patients recorded as having undergone a radical nephrectomy (RN). Patients were included in this study if an International Classification of Diseases code (ICD-10) for malignant neoplasm of the kidney or malignant neoplasm of the renal pelvis (C64 or C65) was present in any of the seven diagnosis fields and an Office of Population Censuses and Surveys operative procedure code (OPCS-4) indicating nephrectomy and excision of perirenal tissue, nephroureterectomy not elsewhere classified, bilateral nephrectomy, nephrectomy not elsewhere classified, other specified total excision of kidney, unspecified total excision of kidney, other specified partial excision of kidney or unspecified partial excision of kidney was present in any of the four operative procedure fields (M021, M022, M023, M025, M028, M029, M038 or M039, respectively). Patients were excluded from the study if their age fell outside of the range 17-90 years and on this basis 69 patients were excluded. Overall 17,308 patients were included.

5.5.2 Results (Radical nephrectomy)

Descriptive statistics of the entire cohort of 17,308 patients are shown in table 5.7. Just under one half of the patients undergoing RN (45.5%) were 65 years of age or older. Approximately two-thirds were men (63.0%). The proportion of patients admitted as an emergency fell from 14.0% to 7.5% over the study duration. The mean annual hospital volumes of RN increased over the study duration. The mean patient age and proportion of operations carried out on men did not seem to change (table 5.8). Waiting time duration increased by almost 6 days over the entire study period. Mean length of stay fell by about one day from 11.7 days in 1995/1996 to 10.8 days in 2001/2002. In-hospital mortality rates also fell over the study duration from 2.0% in 1995/1996 to 1.5% in 2001/2002, although this was not statistically significant.

There was a statistically significant increase in waiting time duration with age. For example, patients less than 55 years waited 20.8 days for admission for surgery, compared to 26.1 days for those aged over 80 years (table 5.9). Men waited longer than women. Older patients had a longer length of stay than younger patients (table 5.9). For example patients aged over 80 years stayed about 5½ days longer than those aged under 55 years. Men had a shorter length of stay than women. There did not appear to be any significant difference in length of stay for those who waited less than compared to greater than four weeks for admission. Patients admitted as an emergency had a length of stay one week longer than those admitted electively (table 5.9).

In-hospital mortality rates increased with age (table 5.9). For example, those aged 55 years or less had an in-hospital mortality rate of 0.6% compared to 4.7% in those older than 80 years. In-hospital mortality was also slightly higher in men compared to women. There did not appear to be any statistically significant association between waiting time duration and in-hospital mortality. Furthermore, in-hospital mortality was almost 2.5 times higher in those admitted as an emergency compared to those admitted electively. Patients who died in hospital tended to stay longer than those who were discharged (15.8 days and 11.1 days, respectively).

The national number of RNs performed per year increased by approximately 20% from 2254 in 1995 to 2671 in 2001 (table 5.10). Over the same period the mean annual hospital volume of RN increased by about 40% from 17 in 1995 to 24 in 2001. However, in this period the total number of hospitals performing RN fell from 198 hospitals to 162 hospitals. The annual number of laparoscopic RNs performed nationally increased from 7 in 1995 to 84 in 2002 and the number of hospitals recorded as performing this procedure increased from 7 hospitals in 1995 to 24 hospitals in 2001. The annual number of partial nephrectomies also increased from 49 to 108 and these were performed in 35 hospitals in 1995 compared to 52 hospitals in 2002 (table 5.10).

5.5.3 Discussion (Radical nephrectomy)

The annual number of RNs performed in England between 1995 and 2002 has increased by approximately one fifth and this was accompanied by an increase in annual hospital volume of about two fifths. There has also been a large increase in the number of laparoscopic and partial RNs. Although waiting time has increased over the study period, the proportion of patients admitted as an emergency has fallen. Average length of hospital stay has fallen over this time period, although there was no significant change in in-hospital mortality rates. Length of stay was higher in older patients, in female patients and in those admitted as an emergency. In-hospital mortality was higher in older patients, in male patients and in those admitted as an emergency.

Limitations of the data

First, the 20% increase in the annual number of RNs observed over this study may in part be explained by the 2% annual increase in the incidence of renal malignancy also reported over this period. However, it may also be explained by lower thresholds for surgical intervention, by improvements in the accuracy and coding of clinical data, and also by the increased use of diagnostic radiology scans. It is not possible to determine the relative contributions of these effects from the present data. In contrast to RP and RC, surgery is the only radical treatment available to patients with renal cell carcinoma (see Chapter 2). The increase in surgical activity therefore cannot be explained by increasing numbers of patients choosing surgery in preference to other therapies, which at least in theory could account for some of the increase in annual numbers of RPs and RCs performed over the same period. Second, although in-hospital mortality rates were observed to fall from 2.0% to 1.5% over the study, this could reflect improvements in the quality of surgical care, but also could be related to the simultaneous fall in the length of hospital stay also observed over this period. As mentioned in the discussion section for RC, this explanation cannot be ruled out as shorter lengths of hospital stay increase the chances of observing higher mortality rates in the time period following discharge. [Goldacre M et al, 2002; Jencks S et al, 1988; Henderson J et al, 1989; Gill L et al]

The finding that the proportional increase in the annual hospital volume of RN was about twice the proportional increase in the national number of RN was surprising. A number of explanations could account for this. First, this could suggest a degree of centralisation of cancer services for RN in England. However, National Guidance recommending that local hospitals should not perform RN in cases where this procedure was likely to be complex (e.g. for tumours invading major blood vessels, or for patients with von Hippel Lindau disease) was issued only in 2002 and therefore should not affect the results of the present study. [National Institute of Clinical Excellence, 2002] Second, the number of hospital trusts in England submitting data to the HES database has fallen over this period, partly due to hospital mergers, and this may also explain the observed increase in hospital volume. [Department of Health, 2004]

Demographic characteristics of the patients included within this study are similar to those included within several previous studies of RN. [Taub D et al, 2004; Mejean A et al, 1999] The average length of stay observed in this study was 11.2 days. This compares with a French study of 656 patients undergoing RN between 1986-1997 that reported a length of stay of 11 days [Mejean A et al, 1999], but contrasts with a nationwide US study of the Medicare database (only including patients over 65 years), which reported a length of stay of 7.5 days. [Goodney P et al, 2003]

The surgical approach clearly also influences the length of stay following RN. In a single centre US study, length of stay for open nephrectomy versus laparoscopic nephrectomy was 3.6 days versus 1.7 days. [Shuford M et al, 2004] In this study, the mean length of stay for laparoscopic nephrectomy was 8.4 days compared to 11.3 days for the open procedure. A national UK audit of laparoscopic nephrectomy for a number of indications between 2001 and 2002 reported a median post-operative length of stay of 4 days in 263 patients. [Keoghane S et al, 2004] Of these cases, 113 (43%) were performed for cancer. Although the study periods do not overlap exactly, in the final year of this study 84 RNs were identified that were coded as having been performed laparoscopically. It is also important to note that the present study included patients only from England, whereas the nationwide audit included patients from elsewhere in the UK. Without formal case note validation it is not possible to determine how many of the patients included in these two studies overlap. In comparison with the US, in the UK the proportion of RNs carried out by a laparoscopic approach is very small, but increasing rapidly. [Allan J et al, 2001]

In the present study, the in-hospital mortality rate was 2.1%. This was lower than a national US study of 58,990 Medicare patients undergoing RN between 1994-1999 where the mortality rate was 3%. [Birkmeyer J et al, 2002] However, considering only those aged over 65 years in our study, the in-hospital mortality rate was 2.9%, very similar to this national US study. However, a large single centre French study of 656 patients reported a postoperative mortality rate of only 0.6% (CI: 0.2-1.7%), considerably lower than either our national study or the US national study. [Mejean A et al, 1999] Another single centre study between 1995-2002 of 1049 patients in the US undergoing RN reported a peri-operative mortality rate of 0.2%. [Stephenson A et al, 2004] Again, as for RC, this illustrates the low mortality rates that can be achieved in some centres, but it is not clear how generalisable these results are on a national level given the potential role of confounding factors such as differences in disease severity and degree of comorbidity. Our finding of a non-significant trend over time towards declining in-hospital mortality also concurs with a similar finding from the US between 1994-1999. [Goodney P et al, 2002] However, it is difficult to interpret the differences between our national UK results and those from elsewhere without further details regarding disease severity, comorbidity, and discharge policies.

5.6 Conclusions

This thesis has utilised the HES database because it is the only source of national information on all hospital admissions in the NHS in England. Moreover, the HES database also spans a significant time period therefore allowing for patterns and trends to be elucidated. [McKee M et al, 1997; Bain M et al, 1997; Lewsey J et al, 2000; McKee M, 1993] Since January 2004, however, the British Association of Urological Surgeons Cancer Registry has collected detailed clinical data on all complex urological cancer procedures performed in NHS Trusts and independent sector hospitals in the UK. [Directory of Clinical Databases, 2004] Given adequate coverage and data quality, this clinical database should allow future studies to be performed that will address some of the limitations associated with the use of administrative databases, such as poor accuracy of clinical coding, lack of information on disease severity and outcomes other than mortality, and a perceived remoteness of data collection and consequent loss of data 'ownership' from clinicians. Despite these limitations, the consistency of the observed demographic trends over time within this study and the face validity of the observed associations between patient demographics and outcomes suggest that the results of this study are credible.

With the advent of clinical governance and revalidation, all clinicians need to provide up-to-date detailed information about their own practices and outcomes [General Medical Council, 2004] This study will allow local providers to compare their immediate short-term outcomes following radical urological cancer surgery with those of national figures and hence will be useful indicators for comparative local audit and clinical governance.

5.7 Tables

Table 5.1

Characteristics of 6166 patients undergoing radical prostatectomy in England

Characteristic		Number of patients	%
Age	<55	600	9.7
	55-59	1124	18.2
	60-64	1885	30.6
	65-69	2001	32.5
	70-74	498	8.1
	≥75	54	0.9

Table 5.2

Radical prostatectomy in England 1995-2002 – patient characteristics and outcome

Year	Annual Procedural volume	Mean annual hospital volume (SD)	Emergency admissions (N,%)	Mean age (SD) in years	Mean waiting time (SD), days	Mean length of stay (SD), days	In-hospital mortality (N, %)
1995/1996	284	9 (8)	2 (0.7)	62.3 (5.8)	39.9 (44.3)	9.6 (6.6)	2 (0.7)
1996/1997	533	10 (5)	9 (1.7)	62.6 (5.8)	42.9 (33.1)	9.7 (5.8)	0 (0.0)
1997/1998	563	10 (6)	6 (1.1)	62.4 (5.7)	40.1 (30.7)	9.1 (5.3)	3 (0.5)
1998/1999	746	12 (8)	6 (0.8)	62.9 (5.6)	38.7 (36.1)	8.9 (4.9)	4 (0.5)
1999/2000	996	17 (12)	7 (0.7)	62.6 (5.8)	38.8 (30.8)	8.3 (5.6)	1 (0.1)
2000/2001	1293	21 (15)	6 (0.5)	62.6 (5.9)	44.7 (35.9)	8.0 (5.8)	1 (0.1)
2001/2002	1751	26 (17)	5 (0.3)	62.6 (5.8)	44.7 (37.6)	7.2 (3.7)	0 (0.0)
P value for trend	<0.001	<0.001	0.001	0.704	<0.001	<0.001	0.008

Table 5.3

Waiting time, length of stay and in-hospital mortality by patient characteristic for radical prostatectomy in England

Characteristic (Number of patients)	Mean waiting time (SD), days	Mean length of stay (SD), days	In-hospital mortality (N, %)
All patients (6166)	32.3 (35.5)	8.2 (5.2)	11 (0.2)
Age			
<55 (600)	37.7 (29.5)	7.4 (3.8)	0 (0.0)
55-59 (1124)	42.6 (37.0)	7.8 (4.1)	0 (0.0)
60-64 (1885)	41.4 (32.3)	8.4 (4.7)	2 (0.1)
65-69 (2001)	43.4 (37.2)	8.4 (5.7)	7 (0.4)
70-74 (498)	45.1 (39.8)	8.8 (7.1)	0 (0.0)
≥75 (54)	45.5 (65.1)	11.9 (11.1)	2 (3.7)
Missing (4)			
P value for trend	0.001	<0.001	0.001
Waiting time			
0-4 weeks (2265)	16.2 (7.9)	8.4 (5.8)	4 (0.2)
>4 weeks (3563)	58.8 (36.3)	8.2 (4.7)	6 (0.2)
Missing (338)			
P value for trend	-	0.724	0.954
Method of admission			
Elective (6120)	42.3 (35.5)	8.2 (5.1)	10 (0.2)
Emergency (41)*	-	11.6 (12.9)	1 (2.4)
Missing (5)			
P value for trend	-	<0.001	0.010

*40 patients who were admitted as emergencies had missing data relating to waiting time duration.

Table 5.4

Characteristics of 8228 patients undergoing radical cystectomy in England

Characteristic	Number of patients	%
Age		
<55	896	10.9
55-59	870	10.6
60-64	1274	15.5
65-69	1734	21.1
70-79	3105	37.8
≥80	346	4.2
Sex		
Male	6209	75.6
Female	2007	24.4

Table 5.5

Radical cystectomy in England 1995-2002 – patient characteristics and outcome

Year	Annual Procedural volume	Mean annual hospital volume (SD)	Emergency admissions (N, %)	Mean age (SD) in years	Men (N,%)	Mean waiting time (SD), days	Mean length of stay (SD), days	In-hospital mortality (N, %)
1995/1996	1013	10 (7)	66 (6.5)	66.1 (9.2)	768 (75.9)	27.9 (41.8)	20.7 (12.7)	54 (5.3)
1996/1997	1072	10 (6)	82 (7.7)	66.1 (9.2)	807 (75.3)	28.4 (34.8)	19.8 (12.4)	51 (4.8)
1997/1998	1172	11 (8)	95 (8.1)	66.9 (8.9)	864 (73.7)	27.1 (32.0)	19.2 (13.5)	58 (5.0)
1998/1999	1291	13 (8)	77 (6.0)	66.5 (9.2)	961 (74.4)	25.5 (22.7)	19.4 (13.9)	69 (5.3)
1999/2000	1199	12 (8)	75 (6.3)	66.2 (9.3)	926 (77.2)	25.5 (24.2)	18.9 (15.9)	49 (4.1)
2000/2001	1225	13 (9)	65 (5.3)	66.6 (9.2)	954 (77.9)	26.9 (24.2)	18.1 (13.7)	44 (3.6)
2001/2002	1256	13 (8)	61 (4.9)	66.6 (8.9)	929 (74.0)	26.3 (23.3)	18.7 (12.5)	45 (3.6)
P value for trend	<0.001	<0.001	0.002	0.325	0.804	0.071	<0.001	0.008

Table 5.6

Waiting time, length of stay and in-hospital mortality by patient characteristic for radical cystectomy in England

Characteristic (Number of patients)	Mean waiting time (SD), days	Mean length of stay (SD), days	In-hospital mortality (N, %)
All patients (8228)	26.7 (29.1)	19.2 (13.6)	370 (4.5)
Age			
<55 (896)	24.8 (37.5)	17.7 (10.4)	15 (1.7)
55-59 (870)	24.9 (25.8)	18.2 (11.4)	14 (1.6)
60-64 (1274)	27.6 (34.3)	18.2 (11.8)	42 (3.3)
65-69 (1734)	26.5 (28.3)	18.9 (14.2)	67 (3.9)
70-79 (3105)	27.4 (25.6)	20.0 (13.5)	196 (6.3)
≥80 (346)	27.9 (23.1)	23.9 (24.3)	36 (10.3)
Missing (3)			
P value for trend	0.006	<0.001	<0.001
Sex			
Male (6209)	27.4 (30.2)	18.9 (13.5)	262 (4.2)
Female (2007)	24.6 (25.1)	20.3 (13.9)	107 (5.3)
Missing (12)			
P value for trend	0.001	<0.001	0.037
Waiting time			
0-4 weeks (4792)	14.1 (7.6)	18.6 (12.4)	106 (4.1)
>4 weeks (2498)	51.0 (38.2)	18.5 (14.3)	109 (4.4)
Missing (938)			
P value for trend	-	0.941	0.813
Method of admission			
Elective (7704)	26.7 (29.1)	18.6 (13.0)	330 (4.3)
Emergency (521)*	-	28.5 (18.1)	40 (7.7)
Missing (3)			
P value for trend	-	<0.001	<0.001

*519 patients who were admitted as emergencies had missing data relating to waiting time duration.

Table 5.7

Characteristics of 17,308 patients undergoing radical nephrectomy in England

Characteristic		Number of patients	%
Age	<55	3806	22.1
	55-59	1904	11.0
	60-64	2378	13.8
	65-69	2962	17.2
	70-79	4889	28.3
	>80	1320	7.7
Sex	Male	10887	63.0
	Female	6387	37.0

Table 5.8

Radical nephrectomy in England 1995-2002 – patient characteristics and outcome

Year	Emergency admissions (N, %)	Mean age (SD) in years	Men (N, %)	Mean waiting time (SD), days	Mean length of stay (SD), days	In-hospital mortality (N, %)
1995-1996	314 (14.0)	63.3 (12.3)	1421 (63.4)	21.2 (26.7)	11.7 (8.2)	46 (2.0)
1996-1997	260 (11.2)	64.1 (11.8)	1446 (62.5)	21.7 (25.4)	11.6 (11.1)	46 (2.0)
1997-1998	277 (11.8)	64.1 (11.9)	1454 (62.2)	23.1 (28.9)	11.5 (9.6)	53 (2.3)
1998-1999	283 (11.4)	63.9 (11.9)	1572 (63.5)	23.0 (26.5)	11.3 (9.2)	63 (2.5)
1999-2000	247 (9.5)	64.3 (12.2)	1621 (62.5)	23.6 (24.3)	11.1 (8.3)	63 (2.4)
2000-2001	244 (9.3	64.0 (12.2)	1660 (62.9)	24.9 (25.6)	10.8 (8.2)	44 (1.7)
2001-2002	199 (7.5)	63.9 (12.1)	1713 (64.2)	27.0 (29.5)	10.8 (9.7)	40 (1.5)
P value for trend	<0.001	0.201	0.470	<0.001	<0.001	0.134

Table 5.9 Waiting time, length of stay and in-hospital mortality by patient characteristic for radical nephrectomy in England

Characteristic (Number of patients)	Mean waiting time (SD), days	Mean length of stay (SD), days	In-hospital mortality (N, %)
All patients (17308)	23.6 (26.8)	11.2 (9.2)	355 (2.1)
Age			
<55 (3806)	20.8 (27.5)	9.4 (6.3)	23 (0.6)
55-59 (1904)	21.2 (20.7)	10.4 (11.4)	13 (0.7)
60-64 (2378)	23.9 (27.9)	10.5 (7.2)	49 (2.1)
65-69 (2962)	24.1 (24.4)	11.1 (9.6)	54 (1.8)
70-79 (4889)	25.9 (29.1)	12.4 (9.7)	154 (3.2)
≥80 (1320)	26.1 (26.1)	14.9 (11.1)	62 (4.7)
Missing (49)			
P value for trend	<0.001	<0.001	<0.001
Sex			
Male (10887)	24.2 (27.5)	11.1 (9.1)	249 (2.3)
Female (6387)	22.7 (25.6)	11.5 (9.3)	104 (1.6)
Missing (34)			
P value for trend	0.001	0.001	0.003
Waiting time			
0-4 weeks (10656)	13.5 (7.5)	10.2 (7.3)	187 (1.8)
>4 weeks (3825)	52.0 (38.4)	10.3 (7.2)	58 (1.5)
Missing (2827)			
P value for trend	-	0.233	0.180
Method of admission			
Elective (15468)	23.6 (26.8)	10.4 (8.3)	274 (1.8)
Emergency (1824)	-	18.0 (12.7)	81 (4.4)
Missing (16)			
P value for trend	-	<0.001	<0.001

*1819 patients who were admitted as emergencies had missing data relating to waiting time duration

Table 5.10: Annual number of radical nephrectomies performed in England and mean hospital annual volumes of radical nephrectomies performed in England between 1995-2002

Year	Annual Procedural volume	Mean (SD) annual Hospital volume	Number of hospitals performing RN	Annual number of laparoscopic RN	Number of hospitals performing laparoscopic RN	Annual Volume of partial RN	Number of hospitals performing partial RN
1995-1996	2254	17(10)	198	7	7	49	35
1996-1997	2319	17(9)	197	4	4	69	47
1997-1998	2354	18(10)	196	4	4	67	41
1998-1999	2476	19(11)	189	5	5	85	44
1999-2000	2595	22(14)	176	13	6	83	42
2000-2001	2639	24(15)	174	23	13	115	54
2001-2002	2671	24(15)	162	84	24	108	52

Chapter 6

Patterns of emergency readmission following radical urological cancer surgery: are emergency readmission rates a useful measure of surgical outcome?

6.1 Objectives

To describe patterns of emergency hospital readmission in the year following radical urological cancer surgery in England between 1998 and 2001, and to determine predictors of emergency hospital readmission using administrative data.

6.2 Introduction

Routine indicators of the quality of medical and surgical care that are both reliable and meaningful are desired by all stake holders involved in the provision of healthcare. [Birkmeyer J et al, 2004] Both length of stay and mortality are examples of such indicators that have been used with a variety of success. [Dubois R et al, 1997; Silber J et al 1997; Johnson M et al, 2001; Russell E et al, 2003] However, decreasing mortality rates for most major procedures challenge the validity of using mortality as a measure of quality. [Romano P et al, 2002; Singh R et al, 2003] Another variable that has been looked at by those interested in investigating the quality of surgical care is the rate or probability of hospital readmission following an initial surgical intervention. Again this has had mixed success. [Riley G et al, 1993; DesHarnais S et al, 1990; Anderson G et al 1984; Fethke C et al, 1986; Roos G et al 1986; Geraci J et al, 2000]

Readmissions are a result of a complex set of interactions that depend on a number of inputs, almost certainly depending on cultural and geographic factors as well as those that depend on patient and clinician thresholds. [Henderson J et al, 1993; Riley G et al, 193; Ashton C et al 1997; Milne R et al, 1990] Moreover, inferences based on readmission rates depend on a number of assumptions. A higher readmission rate could reflect increased post-operative complications and therefore adverse care. Conversely, high readmission rates may reflect better, more proactive management of patients struggling to manage outside of hospital. Low readmission rates could equally be associated with good care or merely reflect a marginal bed capacity that would limit the number of readmissions possible. For these and other reasons, it has been argued that only readmissions that are emergencies or occur secondary to complications of care should be used as outcome measures, as these are unlikely to be part of any planned components of care. [Milne R et al, 1990]

The objectives of this study were: first, to describe patterns of emergency readmission to hospital after discharge following radical urological cancer surgery in England using the Hospital Episode Statistics (HES) database. Second, to examine the associations between emergency readmissions and risk factors that might increase the probability of patients undergoing such a readmission.

6.3 Methods

Data

Through processes of internal data linkage and using the unique HES identification number, it is possible to study patterns of readmission to all NHS hospitals in England using the HES database. Data were included for the years 1998/1999 to 2000/2001 for all patients recorded as having undergone a radical prostatectomy (RP), radical cystectomy (RC) or radical nephrectomy (RN) (see Chapter 5). Overall, 14,460 patients were included.

Readmissions

Data were also extracted to determine the number of emergency readmissions to hospital over the year following the date of admission for surgery, which was used as a proxy for the date of surgery. Readmissions were linked to the admission in which the surgery occurred through the use of the HES identification number, which uniquely identifies patients across the HES database. This number was only available for years subsequent to and including the year 1997-1998. The main outcome measure considered in this study was the odds of a patient undergoing any emergency readmission to hospital in the year following radical urological cancer surgery. The number of patients discharged from hospital following surgery for each procedure was the denominator for all readmission analyses. Patients who died during the index admission cannot be readmitted and are excluded from further analysis. This approach is similar to that used elsewhere. [Ashton C et al,1997; Kiefe C et al, 1999]

Definitions

Waiting time within the HES database is defined as the time in days from the date on which it was decided to admit the patient for surgery to the date of admission to hospital when surgery took place. Patient comorbidity was defined using the Dartmouth-Manitoba adaptation of the Charlson score, which is calculated from the sum of weighted diagnosis and procedure codes representing differing comorbid conditions (see chapter 4). [Charlson M et al, 1987; Romano P et al, 1993] This score was calculated from diagnosis and operative procedure codes present within the index surgical admission and also from admissions that occurred over the year preceding surgery.

Statistical analysis

Univariate logistic regression was used to examine relationships between the odds of undergoing emergency hospital readmission in the year following surgery on the one hand and patient demographics, presence or absence of comorbidity, and method of admission to hospital for the index procedure (emergency versus planned) on the other. All p-values are two-sided and a p-value of <0.05 was defined as significant. All data analyses were performed using Stata Statistical software version 8.2.

6.4 Results

The demographic characteristics, comorbidity scores and unadjusted short-term outcomes of the 14,460 patients undergoing radical urological cancer surgery are presented in table 6.1. Patients undergoing RC had the highest comorbidity scores, the longest length of stay and highest mortality rates, whereas patients undergoing RP had the shortest length of stay and lowest mortality rates. Those undergoing RN were more likely to be admitted as an emergency than those undergoing RC or RP.

Overall, and excluding those patients who had died during the index admission, about 20%, 40% and 25% of patients undergoing RP, RC and RN, respectively, had undergone emergency readmission for any cause in the year following surgery (table 6.2). Patients who underwent RC tended to spend a slightly greater number of days in hospital following emergency readmission in the year following surgery than patients undergoing either RP or RN (table 6.2). It was observed that the procedure with the highest in-hospital mortality rate (RC) also had the highest rate of readmission.

Figure 6.1 demonstrates patterns of emergency readmission over the year following surgery. For all procedures there was an early peak in readmissions followed by a decline to a background rate. This peak occurred slightly later for RC and RN than for RP, which in part reflects the shorter length of stay following RP. For RP, just under two fifths (38%) of the total proportion of emergency readmissions in the year following surgery occurred within 60 days of admission for surgery. In contrast, for RC and RN only about one quarter (24%) and one fifth (20%), respectively of the year's emergency readmissions occurred within this time period (figure 6.1).

Predictors of the odds of undergoing emergency hospital readmission in the year following surgery are shown in table 6.3. Although the odds of emergency readmission increased with increasing age for all three procedures, this was only statistically significant for patients undergoing RN. Patient sex did not appear to be a significant predictor of undergoing emergency readmission for RC or RN. However, patients with greater degrees of comorbidity were more likely to undergo emergency readmission than those with no comorbidity for all three procedures. Increasing waiting time was only a significant predictor of readmission for those undergoing RN. Patients undergoing surgery after an emergency admission were more likely to be readmitted as an emergency following all three procedures, although this effect was not statistically significant for RP (table 6.3).

Unadjusted emergency readmission rates in the year following surgery varied widely between hospitals from zero to 100% (figure 6.2). (All readmissions were attributed to the hospital in which surgery took place, regardless of where the readmissions occurred.) However, using a random effects multi-level model, and adjusting for age, sex and comorbidity, the variance in emergency readmission rates between hospitals diminished markedly, being least for RC (0.02), most for RP (0.13), and with the variance for RN being 0.04.

6.5 Discussion

In summary, these results show that hospitals performing RP, RC and RN should plan for about one fifth, two fifths and one quarter of their patients, respectively, to undergo emergency readmission within a year of surgery. This represents a significant workload. Older patients, those with increasing degrees of comorbidity and those undergoing surgery following an emergency admission are more likely to be readmitted as an emergency in the year following radical urological cancer surgery. These data may be used to help counsel patients prior to surgery and to help hospitals plan their surgical services.

For all three procedures there was an obvious temporal association between surgery and a peak in the proportion of readmissions occurring within a few weeks of surgery. This peak was followed by a decline to a background level for the remainder of the year. A similar pattern was noted following emergency readmissions after appendicectomy and elective prostatectomy (for benign disease) in a previous English study. [Henderson J et al, 1993] The background level was lower for RP than for RC or RN, reflecting the lower age and lower comorbidity scores of patients undergoing RP. This background level consists of admissions related to longer term complications of surgery, follow-up care relating to the underlying reason for surgery, and admissions that are independent of surgery and would have occurred notwithstanding the fact that surgery took place (e.g. admissions for fractured neck of femur). [Riley G et al, 1993; Henderson J et al, 1993] For these reasons, although some background readmissions may not be directly related to surgery, the vast majority of the total emergency readmissions are likely to be. [Henderson J et al, 1993; Roos L et al, 1987] Furthermore, by including only emergency readmissions, almost all of the admissions for removal of the urinary catheter inserted during RP have been excluded from this study.

Readmissions are important components of surgical care for patients, clinicians and hospitals. This study has demonstrated that for radical urological cancer surgery procedures it is possible to identify some patient factors that are associated with increased likelihood of undergoing emergency readmission. Furthermore, this study has also demonstrated a large variation in unadjusted emergency readmission rates between hospitals.

Previous work has demonstrated that much of the observed variance in readmission rates between patients and hospitals is not explained solely by adjustment for patient characteristics or comorbid disease. [Ashton C et al, 1997; Zitser-Gurevich Y et al, 1999; Soeken K et al, 1991; Thomas J, 1996] Other characteristics such as socio-economic status and hospital and surgeon factors may also be strongly predictive of readmission. However, some of these hospital and surgeon factors may be random and resistant to statistical modelling and this may explain the low predictive power of readmission models noted in previous studies. [Zitser-Gurevich Y et al, 1999; Rosen A et al, 1992; Thomas J, 1996]

Methodological limitations

There are several methodological limitations associated with this study. First, using readmissions to act as a proxy for the quality of surgical care will only identify those complications of care that necessitate readmission or require further surgical intervention (such as development of urethral strictures following RP). Other complications such as incontinence or impotence following RP may not usually require readmission or surgery, and as a consequence will remain unidentified through this approach. [Potosky A et al, 2002] Identifying complications of care and distinguishing these from pre-existing comorbidities is a process that may be fraught with difficulty. [Geraci J, 2000; Geraci J et al, 1997; Romano P et al, 2002; Iezzoni L et al, 1992] For example, discriminating between a post-operative myocardial infarction and a pre-existing myocardial infarction is often impossible on the basis of diagnosis codes from administrative data. Furthermore, although death and readmission are easily definable measures that are relatively straightforward to achieve coding accuracy and consistency between hospitals, complications of care are not. Administrative databases must therefore develop improved strategies for identifying and coding specific complications, in order to define fully the link between complications and readmissions. [Kiefe C, 1999]

Second, this study was only able to account for post-operative deaths occurring within hospital. This limitation is likely to have diminished the magnitude of some of the findings, as certain groups of patients are more likely to die after discharge from hospital than others (e.g. older patients and those with more comorbidity). Consequently, these patients have a shorter period of time in which they could undergo an emergency readmission. It is envisaged that in the future the HES database will be linked with death certification databases, so that the effect of mortality after hospital discharge may be considered. However, currently there are ethical, logistical and legal reasons hampering the process of acquiring the linked dataset.

Policy implications and future work

The Department of Health in England uses an age and sex-standardised 28-day emergency readmission rate per NHS Trust following all admissions to that trust as a quality and performance indicator within the NHS. [Department of Health, 2004] This might act as a useful incentive to reduce emergency readmissions and to attempt to benchmark performance. However, this study has demonstrated that the effect of the index surgical procedure and the effect of comorbidity markedly influence emergency readmission rates. In addition, for complex procedures such as RC, a large proportion of readmissions will occur after 28 days. Moreover, this study has also demonstrated that much of the observed variance between hospitals in emergency readmission rates may be explained following adjustment for patient factors and also the number and type of procedures that a hospital performs. Until we have a clearer understanding of all the factors that predict hospital emergency readmissions, the uses to which such indicators should be put will remain extremely limited. [Roland M et al, 2005] Future work needs to examine the hospital and surgeon characteristics that effect readmission, together with other patient factors such as disease severity and access to primary care facilities.

6.6 Conclusions

Hospitals performing RP, RC and RN should plan for about one fifth, two fifths and one quarter of their patients, respectively, to undergo emergency readmission within a year of surgery. Readmissions are the result of a complex set of interactions that depend on a number of inputs. In order to use emergency readmission rates as a measure of surgical outcome, future work is required to examine the hospital and surgeon characteristics that effect readmissions, together with patient factors such as disease severity and access to primary care facilities.

6.7 Tables

Table 6.1: Characteristics and short-term outcomes of the 14,460 patients undergoing radical prostatectomy, radical cystectomy and radical nephrectomy in England between 1998 and 2001

Characteristic	RP	RC	RN
Number of patients	3035	3715	7710
Age in years, mean (SD)	62.7 (5.8)	66.5 (9.2)	64.1 (12.1)
Male sex, number (%)	3035 (100.0)	2841 (76.5)	4853 (62.9)
Waiting time in days, mean (SD)	41.3 (34.5)	26.0 (23.7)	23.8 (25.5)
Emergency admission, number (%)	19 (0.6)	217 (5.8)	774 (10.0)
Charlson score, number (%)			
0	2615 (86.2)	1858 (50.0)	4820 (62.5)
1	232 (7.6)	275 (7.4)	888 (11.4)
≥2	188 (6.2)	1582 (42.6)	2010 (26.1)
In-hospital mortality, number (%)	6 (0.2)	162 (4.4)	170 (2.2)
Length of initial stay in days, mean (SD)	8.3 (5.5)	18.8 (14.5)	11.0 (8.6)

RP = radical prostatectomy; RC = radical cystectomy; RN = radical nephrectomy

Table 6.2: Number of patients readmitted at least once as an emergency within 90 days and 1 year after radical urological cancer surgery and number of days spent in hospital in the year after surgery following emergency readmission in England between 1998-2001

	RP* (N=3029)	RC* (N=3553)	RN* (N=7540)
Readmitted within 90 days, number (%)	434 (14.3)	715 (20.1)	889 (11.8)
Readmitted within 1 year, number (%)	553 (18.3)	1392 (39.2)	1883 (25.0)
Total number of days in hospital after emergency readmissions in the year following surgery, mean (SD)†	8.0 (22.8)	18.6 (20.2)	15.6 (20.7)

RP = Radical prostatectomy; RC = Radical cystectomy; RN = Radical nephrectomy

*The number of patients discharged from hospital following surgery was the unit of analysis and therefore patients who died during the surgical admission were excluded from readmission analyses

† Considering only those patients who underwent emergency readmission

Figure 6.1: Proportion of emergency readmissions by week in the year following radical urological cancer surgery in England 1997-2001†

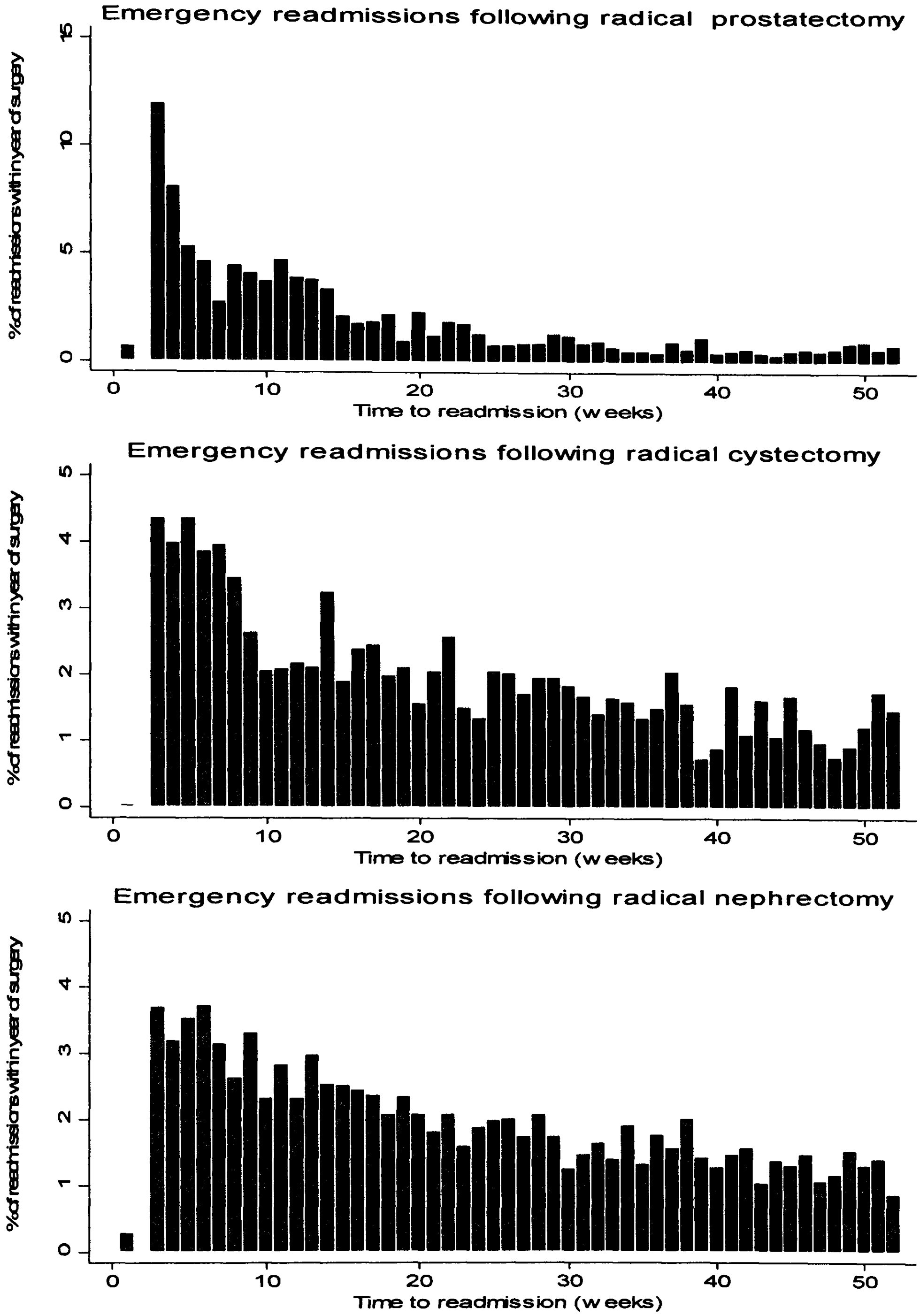
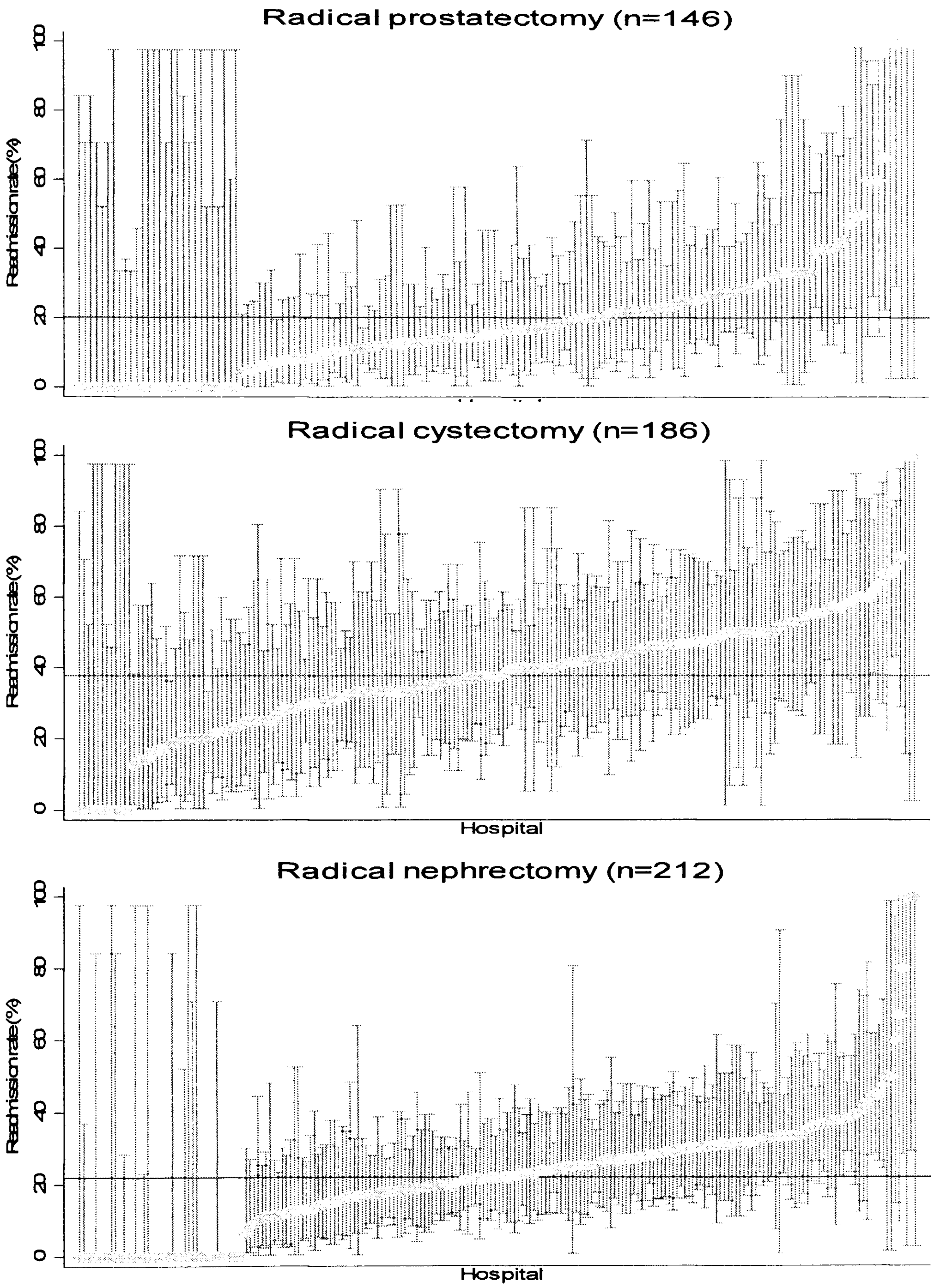


Table 6.3: Predictors of odds of undergoing emergency readmission in the year following radical urological cancer surgery in England 1998-2001

Characteristic	Category	Number of patients	Number (%) readmitted in the year following surgery	Odds ratio (95% CI)	P value
Radical prostatectomy (n=3029)					
Age	>70	280	28 (10.0)	1.1 (0.8-1.6)	0.448
	60-70	1914	380 (19.9)	1.1 (0.9-1.3)	
	<60	835	145 (17.4)	1.0	
Sex	Female	-	-	-	-
	Male	-	-	-	
Charlson score	≥2	187	46 (24.6)	1.6 (1.1-2.2)	0.001
	1	231	58 (25.1)	1.6 (1.2-2.2)	
	0	2611	449 (17.2)	1.0	
Waiting time	> mean	1288	251 (19.5)	1.2 (1.0-1.4)	0.132
	≤ mean	1741	302 (17.3)	1.0	
Method of admission	Emergency	19	5 (26.3)	1.6 (0.6-4.5)	0.367
	Planned	3008	548 (18.2)	1.0	
Radical cystectomy (n=3553)					
Age	>70	1484	525 (35.4)	1.0 (0.9-1.2)	0.735
	60-70	1281	554 (43.2)	0.9 (0.8-1.1)	
	<60	788	313 (39.7)	1.0	
Sex	Female	834	349 (41.8)	1.2 (1.0-1.4)	0.071
	Male	2719	1043 (38.4)	1.0	
Charlson score	≥2	1499	620 (41.4)	1.2 (1.1-1.4)	0.002
	1	258	122 (47.3)	1.6 (1.2-2.1)	
	0	1796	650 (36.2)	1.0	
Waiting time	> mean	1612	585 (36.3)	1.0 (0.9-1.1)	0.970
	≤ mean	1941	807 (41.6)	1.0	
Method of admission	Emergency	199	101 (50.8)	1.7 (1.2-2.2)	0.001
	Planned	3354	1291 (38.5)	1.0	
Radical nephrectomy (n=7540)					
Age	>70	2431	654 (26.9)	1.2 (1.1-1.4)	0.001
	60-70	2619	671 (25.6)	1.2 (1.0-1.3)	
	<60	2472	558 (22.6)	1.0	
Sex	Female	2811	689 (24.5)	1.0 (0.9-1.1)	0.474
	Male	4729	1194 (25.2)	1.0	
Charlson score	≥2	1928	664 (34.4)	2.0 (1.8-2.3)	<0.001
	1	849	236 (27.8)	1.5 (1.3-1.8)	
	0	4763	983 (20.6)	1.0	
Waiting time	> mean	3473	921 (26.5)	1.2 (1.1-1.3)	0.004
	≤ mean	4067	962 (23.7)	1.0	
Method of admission	Emergency	744	271 (36.4)	1.8 (1.6-2.2)	<0.001
	Planned	6793	1612 (23.7)	1.0	

Figure 6.2: Emergency readmission rates by hospital in the year following radical urological cancer surgery in England 1998-2001 ‡



‡Horizontal line on each graph represents the mean hospital readmission rate and the vertical lines represent the upper and lower 95% confidence intervals

Section 4

Volume and outcome relationships in radical urological cancer surgery

Chapter 7

A systematic review and critique of the literature relating hospital or surgeon volume to health outcomes for three urological cancer procedures

7.1 Introduction

Numerous studies have suggested that outcomes for surgical procedures are better if they are performed in high-volume hospitals or performed by high-volume surgeons. [Halm E et al, 2002; Gandjour A et al, 2003; Birkmeyer J et al, 2002; Birkmeyer J et al, 1999; Hillner B et al, 2001; Houghton A et al, 1994; Flood B et al, 1984; Hillner B et al, 2000; Birkmeyer J et al, 2003] Similar results have been found for urological oncology. [Begg C et al, 2002; Yao S et al, 1999] However, in urological cancer care there are also studies challenging the theory that high volume relates to better outcomes. These studies, which tend to be relatively small, produce evidence that lower volume surgeons, surgical residents or community-type hospitals are capable of reproducing the surgical outcomes of the usually larger "centres of excellence". [Mellor A et al, 2002; Cohn J et al, 2002; Gaylis F et al, 1998; Hollenbeck B et al, 2003; Aucamp J et al, 1995]

If a positive association exists between the volume of procedures undertaken by a provider and the outcomes obtained, the reasons for this are not fully understood. First, it is suggested that – as in many other activities – there exists a 'practice makes perfect' phenomenon, which may apply not only to the skills of the surgeon but also to all other aspects of the provision of medical and nursing care. Moreover, this practice makes perfect phenomenon may also include the ability to implement clinical practice guidelines and to practise evidence-based medicine. Second, hospitals or surgeons with better outcomes may develop a better reputation and thus attract additional referrals: the 'selective referral' hypothesis. [Luft H et al, 1987] Last, the relationship between volume and outcome may be explained if high-volume providers care for less sick or lower risk patients: the 'confounding' hypothesis.

These three hypotheses are not mutually exclusive, and they may even interact. With our current knowledge, it is therefore difficult – if not impossible - to predict how health outcomes may change if existing providers were to increase their volumes. Nevertheless, volume-based policies are being implemented in both the USA and Europe in order to try to improve surgical outcomes. [Birkmeyer J et al, 2001; National Institute of Clinical Excellence, 2002] This can be partly understood, because volume as a proxy measure for quality in healthcare is appealing to policymakers, patients and insurance providers given the lack of alternative measures.

Two strategies are commonly used to implement these volume-based policies, either through a reduction in the number of low volume providers by setting minimum volume thresholds or through an increase in the number of high volume providers by centralising care. In the UK, both of these strategies have been advocated by the National Institute of Clinical Excellence (NICE), a government-funded body that provides health-care professionals and the public with guidance on 'best practice'. For example, NICE recommends in the short term that radical surgery for prostate and bladder cancer should be performed by surgeons who carry out at least 5 of either of these procedures per year. In the longer term, these procedures should only be performed at hospitals caring for a population of at least one million people. Similarly, the Leapfrog Group, a coalition of public and private health care purchasers in the United States that aims to improve health care quality by embracing an 'evidence-based' purchasing strategy, has adopted minimum volume standards for a number of high risk surgical procedures. [Leapfrog Group, 2004]

To examine further the volume-outcome relationship for urological cancer surgery, this study reports the results of a systematic review of studies that included patients undergoing radical surgical treatment for cancer of the bladder, kidney and prostate. This review aimed to answer the question whether patients undergoing radical prostatectomy, cystectomy or nephrectomy have improved health outcomes if they are treated by high volume hospitals or surgeons.

7.2 Methods

Search strategy

The search strategy aimed to identify studies describing the relationship between hospital or surgeon volume on the one hand and health outcomes on the other for radical surgical treatment for cancer of the bladder, kidney and prostate. The following electronic databases were searched: MEDLINE (1966-2003), EMBASE (1980-2003), the Health Management Information Consortium, and the Cochrane Library. No time restrictions were placed on the searches of the latter two databases. The searches were performed using both key words and MeSH headings (see Appendix 4). The reference lists of all identified articles were hand searched for other relevant studies and electronic searches were also conducted using the names of key authors who were known to have published widely in this field of study.

Case mix adjustment

Each study was assigned a case-mix score ranging from 0 to 3. [Sowden A et al, 1995; Sowden A et al, 1997] A score of 0 indicated no case mix adjustment; a score of 1 adjustment for demographic variables only; a score of 2 adjustment for demographic variables and co-morbidities and a score of 3 adjustment for demographic variables, co-morbidities and disease severity or stage.

Inclusion criteria

Studies were included if they provided data on health outcomes on the one hand and provider volume on the other. Studies were excluded if they were not community-based, if they extracted data from only one or two providers, or if they did not contain primary empirical evidence (i.e. reviews, letters, editorials, comments and policy statements). Two reviewers (MN and NP, see appendix 1) assessed the retrieved articles for inclusion and exclusion criteria. The same reviewers extracted data from included articles. Disagreements in either study inclusion or data extraction were resolved by a third reviewer (JvdM, see appendix 1).

Data extraction

Data were extracted from each study - separately for hospitals and surgeons - on country of study origin and time period studied, the type of procedure, data source, case mix score, number of patients included, outcome variables, volume categories, and study conclusion. The studies were grouped by surgical procedure and summarised in tabular form commencing with the most recently published (tables 7.1-7.2). Due to the heterogeneity between studies in definitions of volume categories and outcomes, it was not possible to perform a meta-analysis.

7.3 Results

Included studies

Overall, 11 articles were included in the systematic review. Three articles presented data on more than one urological procedure. [Birkmeyer J et al, 2002; Finlayson E et al, 2003; Goodney P et al, 2003] Data relating to different procedures within the same article were considered as separate studies.

12 studies were found relating *hospital* volume to outcomes: 4 studies for radical prostatectomy [Begg C et al, 2002; Yao S et al, 1999; Hu J et al, 2003; Ellison L et al, 2000], 4 for radical cystectomy, [Birkmeyer J et al, 2002; Begg C et al, 1998; Finlayson E et al, 2003; Goodney P et al, 2003] and 4 for radical nephrectomy. [Birkmeyer J et al, 2002; Finlayson E et al, 2003; Goodney P et al, 2003; Sloan F et al, 1986] Four studies were retrieved relating *surgeon* volume to outcomes: 3 studies for radical prostatectomy [Begg C et al, 2002; Hu et al, 2003; Karakiewicz P et al, 1988] and 1 study for radical cystectomy. [Birkmeyer J et al, 2003] Two studies were identified for radical cystectomy that may in part have included the same patients. The first of these studies assessed the effect of hospital volume on outcomes [Birkmeyer J et al, 2002], whereas the second predominantly assessed the effect of surgeon volume on outcomes. [Birkmeyer J et al, 2003] The first study was included only in the section on hospital volume and the second only in the sections on effect of surgeon volume and the combined effects of surgeon and hospital volume.

Country of origin and time period

Ten of the 11 included articles described nationwide studies performed in the US and the other article was a regional study performed in Quebec, Canada. [Karakiewicz P et al, 1998] One article was published in 1986, [Sloan F et al, 1986] and all of the others in 1998 or thereafter, reflecting the recent burgeoning interest in this topic.

Outcomes

Nine of the 11 included articles used a measure of mortality as a primary outcome measure. These included in-hospital and 30 or 60-day mortality. For studies of radical cystectomy or nephrectomy, readmission rates and length of stay were the only other outcome measures used. For studies of radical prostatectomy, longer-term outcomes such as potency, stricture and continence rates were also analysed.

Methodological limitations

In all included studies there were some limitations in the methods of adjustment for disease stage and comorbidity, as none of the studies obtained data directly from patient case notes. The Canadian study used an insurance claims database and was only able to adjust for patient demographics. [Karakiewicz P et al, 1998] Of the American studies, 2 used Medicare/Medicaid data [Yao S et al, 1999; Hu J et al, 2003], 3 used coded discharge summaries [Ellison L et al, 2000; Finlayson E et al, 2003; Sloan F et al 1986], and 3 used a combination of these two data sources. [Birkmeyer J et al, 2002; Birkmeyer J et al, 2003; Goodney P et al, 2003] All of these studies were therefore able to make adjustments not only for patient demographics but also for comorbidity. The two remaining studies used data from a cancer registry linked with the Medicare database and could therefore include some adjustment for disease severity, in addition to adjustment for demographic variables and comorbidities. [Begg C et al, 1998; Begg C et al, 2002]

The 7 articles that used Medicare/Medicaid data were limited to a patient population of over 65 years of age or a population with low income. This may have impaired the accuracy of the information about the total hospital or surgeon volumes, and therefore on the allocation of providers into volume categories. Only 3 of these 7 articles included an explicit description about how they had calculated total provider volume based on an extrapolation to the total case load. [Birkmeyer J et al, 2002; Birkmeyer J et al 2003; Goodney P et al, 2003]

Most articles for reasons of clarity, considered volume as a categorical variable, although some studies reported results with volume expressed as both continuous and categorical variables. In some articles volume categories were based on the number of procedures performed in a year, whereas in others they were based on the number of procedures performed over the entire study period. There was considerable variation in the definition of highest and lowest volume categories between studies.

Volume - outcome relationship

A summary of the data extracted from the included studies is presented in tables 7.1 and 7.2. A result was considered to be statistically significant if the p value was less than 0.05.

For hospital volume, only 1 of the 12 included studies did not demonstrate some improvement of outcomes with higher hospital volumes, either with respect to mortality or other outcomes. [Sloan F et al, 1986] First, of the 3 studies that examined mortality after radical prostatectomy, 2 studies found a lower mortality with increasing hospital volumes [Yao S et al, 1999; Ellison L et al, 2000], and 1 found no change. [Begg C et al, 2002] Furthermore, all 4 studies of this surgical procedure found improvements in other outcomes with increasing hospital volume, but again these improvements were not always statistically significant. Second, for radical cystectomy, one study found a significant decrease in mortality with increasing hospital volume and two studies showed a non-significant decrease. [Begg C et al 1998, 1998; Finlayson E et al, 2003] The one study that examined other outcomes for this procedure found a statistically significant reduction in length of hospital stay but no change in 30-day readmission rate with increasing hospital volume. [Goodney P et al, 2003] Third, for radical nephrectomy, one study found a significant reduction in mortality with increasing hospital volume, one found no real change [Finlayson E et al, 2003], and 1 found a rise in mortality (level of statistical significance was not reported). [Sloan F et al, 1986] The one study that examined other outcomes for radical nephrectomy found that there was a statistically significant but very small lengthening of hospital stay with increasing hospital volume, and no obvious change in 30-day readmission rate. [Goodney P et al, 2003]

Four studies were identified that examined the effect of surgeon volume on outcomes. All of these studies found improved outcomes with higher surgeon volumes, either with respect to mortality or other outcomes. First, for radical prostatectomy, one study found a statistically significant decrease in mortality and one study a statistically non-significant increase in mortality with higher surgeon volumes. [Begg C et al, 2002; Karakiewicz P et al, 1998] Two studies found a statistically significant improvement in other outcomes with increasing surgeon volume. [Begg C et al, 2002; Hu J et al, 2003] Second, for radical cystectomy, one study identified a statistically significant reduction in mortality with surgeon volume. [Birkmeyer J et al, 2003] No studies were identified which examined the effect of surgeon volume on outcomes for nephrectomy.

Three studies examined the combined effect of hospital and surgeon volume on outcomes. [Birkmeyer J et al, 2003; Begg C et al, 2002; Hu J et al, 2003] One study found that mortality after cystectomy was lower in high volume hospitals or with high volume surgeons, but these effects were smaller, however still statistically significant, when both hospital volume and surgeon volume were included in the same statistical model. [Birkmeyer J et al, 2003] A second study of radical prostatectomy found that outcomes other than mortality were better in high volume hospitals and high volume surgeons. However, only the effect of surgeon volume remained statistically significant when both hospital and surgeon volume were included in the same model. [Hu J et al, 2003] A third study found that postoperative and late urinary complications occurred less frequently in high volume hospitals and with high volume surgeons in analyses when both these factors were included in the same statistical model. [Begg C et al, 2002]

7.4 Discussion

This review found that outcomes after radical prostatectomy and cystectomy are on average likely to be better if they are performed in high volume hospitals. For these two procedures, all eight studies found improvement in at least one of the outcomes with increasing volume, albeit these were not always statistically significant. For radical nephrectomy, the evidence for a volume-outcome relationship is much less clear, as different studies have produced conflicting results.

Outcomes after radical prostatectomy and cystectomy also seem to be better if these procedures are performed by high volume surgeons. All four studies showed outcomes that were statistically significantly better with increasing volume. However, this statistical improvement in outcomes was not always clinically meaningful. No studies of the effect of surgeon volume on outcomes after nephrectomy were identified.

All studies that looked at the combined effect of *hospital and surgeon volume* on outcomes, either after radical prostatectomy or cystectomy, suggest that both hospital and surgeon volume are independent determinants of outcome. However, models that include hospital and surgeon volume together suggest that high-volume hospitals have better outcomes, in part because of the effect of surgeon volume and vice versa.

Methodological limitations of the review

Definitions of outcome

The studies included in this review used different measures of surgical outcome. For example, the definition of mortality, although one of the most easily measurable outcomes, varied between in-hospital, 30-day and 60-day mortality. In-hospital mortality is unsatisfactory as an outcome measure because it depends on variations in length of stay among hospitals, which may attenuate any existing volume-outcome relationships. [Johnson M et al, 2002; Goldacre M et al, 2002] A recent study performed in the UK has demonstrated that the mortality associated with the treatment for invasive bladder cancer was 2 to 3 times higher at 3-months than the 30-day mortality, which suggests that modest changes in length of stay could have a considerable impact on in-hospital mortality. [Chahal R et al, 2003] In order to identify deaths within a longer period of time from the index admission, administrative databases may need to be linked with death certification or mortality databases. [Goldacre M et al, 2002; Smith T, 1993]

A further problem of using mortality as an outcome is that post-operative death is a relatively rare event, especially for radical prostatectomy. For this reason, outcomes other than mortality are important as they occur more frequently. However, these other outcomes are more difficult to define and therefore less reliably captured in large routinely collected databases. [Iezzoni L et al, 1992] One of the included studies reported the results of a validation of urinary stricture rates after radical prostatectomy.

Definitions of case mix

All studies except one included in this review were able to adjust at least for demographic variables and comorbidity. Two of these studies could also adjust for disease severity as well on the basis of data obtained through linkage with cancer registries. Most studies recognised comorbid conditions on the basis of information obtained from the index admission and also from previous admissions that had occurred within a defined period, identified from the same database as that used for the volume-outcome analysis. Adjusting for comorbidity could be considered as more important than adjusting for disease severity as most studies considered short-term outcomes, which may depend more strongly on comorbidity than disease severity.

No study explicitly addressed directly the validity of the methods to determine comorbidity, but in most cases they were based on a comorbidity index developed for use with ICD-9-CM administrative databases. [Begg C et al, 1998; Romano P et al, 1993; Ghali W et al, 1996; Charlson M et al, 1987] Administrative data are known to be limited in their ability to adjust for the presence of comorbidity, and this may lead to either an under- or overestimation of the effect of volume on outcome. [Iezzoni L et al, 1992; Iezzoni L, 1997; Roos L et al, 1987; Jencks S et al, 1988; Sommer S et al, 2001; Cleves M et al, 1997; Khwaja H et al, 2002] Nevertheless, it seems rather unlikely that inadequate case-mix adjustment could fully explain the volume-outcome relations described in the identified studies, because in some studies the prevalence of comorbid conditions varied only to a small degree according to provider volume and in fact was found to be higher in many of the high-volume providers. [Birkmeyer J et al, 2002; Birkmeyer J et al, 2003]

Statistical analysis

A difficulty in comparing the results across studies was although almost all studies grouped volume of providers into categories, the cut-off points and the methods of categorisation varied between studies. It was not always clear how the cut-off points for the volume categories were derived, or whether these were defined before or after some analysis of the data had taken place. If cut-off points were not set *a priori*, this increases the chance of producing 'false-positive results' or, in other words, demonstrating volume-outcome relationships that in reality do not exist. A further disadvantage of the categorisation of volume is that data relationships may be lost and that additional statistical error may be introduced, which in turn increases the chance of producing 'false-negative results'. Analysing volume as a continuous variable is a statistically more powerful approach provided that the nature of the volume-outcome relationship (linear or non-linear) can be adequately defined. The predominance of studies considering volume as a categorical variable can be understood as volume categories allow studies to cope in a simple way with non-linear relationships between volume and outcome. Furthermore, results derived from volume categorisation can be easily interpreted in a clinical context and provide volume thresholds on the basis of which volume-based policies can be directly defined. In this respect, it is important to recognise that in some studies volume categories were based not on the number of procedures performed over one year, but on the number of procedures performed over the entire study period.

Most studies did not account for the statistical phenomenon of 'clustering', which refers to the finding that the outcomes of two patients treated by the same provider tend to be more similar than the outcomes of two patients treated by different providers. [Lee KJ et al, 2005; Birkmeyer J et al, 2002; Birkmeyer J et al, 2003; Begg C et al, 2002; Finlayson E et al, 2003] It has been demonstrated that if clustering is ignored this may lead to erroneous conclusions about the relationship between volume and outcome. [Panageas K et al, 2003] For example, a re-analysis of data from an earlier study on outcomes after radical prostatectomy found that adjustment for clustering widened the confidence intervals of the odds ratio reflecting the effect of lower provider volume on outcome and similarly reduced the statistical significance of the volume effect. [Begg C et al, 2002; Panageas K et al, 2003] However, the same study also indicated that different statistical methods to adjust for clustering produced different results, which demonstrates the need for further methodological work in this area. Another argument to consider clustering explicitly is that it may help to identify care processes associated directly with good outcomes. [Panageas K et al, 2003; Laine C et al, 2003] Insight into these processes may also help to define policies aimed at improving surgical outcomes independent of provider volume.

Only one study investigated the effect on outcomes of changing volume over time (longitudinal analysis), which would predict what would happen to outcomes should lower volume providers increase their volumes. [Yao S et al, 1999] This study found differences in mortality and complication rates following radical prostatectomy according to volume differences *between hospitals* but did not according to volume differences *within hospitals*. A longitudinal approach is important because it ensures that provider characteristics that may affect the relationship between volume and outcome remain constant. However, the same study also reported that outcomes changed over time, especially length of stay, irrespective of changes in volume. This illustrates the difficulty that longitudinal studies have in disentangling the effects of improvements of surgical practice, over time from those of changes in volume, especially for relatively new procedures such as radical prostatectomy. [Oliver S et al, 2003; Leibman B et al 1998; Chang P et al, 2002] In other words, when the rapid process of technology development is taken into consideration, the definition of a volume threshold should be specific to each longitudinal time period, with a regular and dynamic review of the evidence.

Volume-based health policies

Since the volume and outcome relationship was originally reported over twenty years ago, clinicians, health care policy makers and politicians have often failed to agree policies whereby health care involving complex or high-risk procedures should be regionalised or minimum volume thresholds enforced. [Luft H et al, 1979; Birkmeyer J, 2000; Epstein A, 2000; Begg C et al, 2003] This is partly because although most authors working in the field agree that there is a relationship between higher volume and improved healthcare outcomes, there is no consensus as to the explanation behind this effect. [Berger et al, 2003] The implementation of volume-based policies in the USA and UK suggests that the "practice makes perfect" hypothesis is considered by some as the predominant explanation. [Kizer K, 2003; Luft H et al, 1979; Birkmeyer J, 2000; Epstein A, 2002; Begg C et al, 2003; Berger D et al, 2003] If a positive association between volume and outcomes based on "practice makes perfect" exists, these policies will *on average* lead to improved outcomes. However, it will always be important to consider the circumstances of each individual provider, as low-volume providers with good outcomes and high-volume providers with relatively poor outcomes also exist. [Kizer K et al, 2003]

Stronger evidence was found in this review that higher volume is associated with better outcomes for radical prostatectomy and radical cystectomy than for radical nephrectomy. This finding is in agreement with other studies that found that the magnitude of the effect of volume on outcome varies greatly among different surgical procedures. [Halm E et al, 2002; Birkmeyer J et al, 2002; Hillner B, 2001; Sowden A et al, 1997] Although there are no agreed criteria to define the complexity of surgical procedures, radical nephrectomy is generally considered to be the least complex procedure in terms of the level of surgical skill required, compared with either radical prostatectomy or cystectomy. In other words, the size of the effect of volume on outcome seems to depend to some extent on the level of surgical skill required to perform a particular procedure. This lends credence to the predominance of the "practice makes perfect" hypothesis over the "selective referral" or "confounding" hypotheses as explanations for the observed effects of volume on outcomes.

Confounding (high volume providers caring for lower risk patients) as a significant mechanism underlying the effects of volume on outcome becomes less likely given the observation in many studies that adjustment for case-mix did not reduce the effect of volume on outcome. It is more difficult to exclude selective referral (providers with better reputations attracting more referrals) as an important factor since most evidence on the volume-outcome relationship originates from studies performed in the US. The importance of selective referral would be clearer if more data from other countries and health care systems were available. For example, the health care system in the UK differs from that in the US in that most British patients and their doctors have little control over where a surgical treatment is delivered and even less by whom the surgical procedure is performed, although current initiatives increase opportunities for patient choice in the UK.

Large numbers of radical urological cancer procedures are now performed using a laparoscopic approach, particularly for radical nephrectomy. This review could not make a distinction in the included studies between open or laparoscopic approaches. With increasing numbers of laparoscopic urological oncological procedures being performed, further work is required to determine volume-outcome relationships separately for open and laparoscopic procedures.

Implementation of volume-based referral policies requires volume to be defined. [Christian C et al, 2003] In this respect, a number of questions remain to be answered. First, should volume be defined at hospital level, surgeon level or both? It has been demonstrated that the effect of hospital volume on outcomes is in part explained by surgeon volume, but that surgeon volume is not the only contributing factor. [Birkmeyer J et al, 2003] Second, should volume refer to a specific procedure (for example, radical prostatectomy) or to all procedures in a specific surgical area (for example, urological cancer surgery)? Third, should adjustments be made for a hospital's or a surgeon's past experience (for example, use of different criteria for those with years of experience compared to those who have recently just started performing a specific procedure)? Within this context, it is important to note that some studies included data for radical urological cancer procedures that were performed by non-urological surgeons. [Yao S et al, 1999] Even if "practice makes perfect" is accepted as the predominant explanation for volume-outcome relationships, these questions demonstrate the difficulties in developing volume-based policies and the uncertainty of their effect when implemented.

A concomitant advantage of volume-based policies is that outcomes can be measured more precisely through the ability to study larger groups of patients. Adverse outcomes for patients managed by low volume providers may be less related to the performance of the provider and, because of a small group size, more due to chance. [Shahian D et al, 2003] Radical cystectomy, for instance, in common with many other high-risk surgical procedures, is performed too infrequently by most providers to measure reliably many outcomes. It was recently estimated in the UK that it would take most of a surgeon's career to accumulate sufficient cases to eliminate the effect of chance in producing poor surgical outcome. [Singh R et al, 2003] Furthermore, opportunities for the sub-specialist training of future surgeons may be enhanced by the increased experience accrued from centres with higher volumes. In order to quantify the benefits of implementing a volume and outcomes policy strategy, attempts have been made in the US to estimate the number of lives that could be saved by regionalising major surgery in Medicare patients. [Birkmeyer J et al, 1999] For instance, if, as assumed by the investigators, a policy of moving patients from low-volume to higher-volume centres led to a relative reduction of 5% in the in-hospital mortality rates of 3.1% for radical nephrectomy and radical cystectomy, 21 and 7 lives per year might be saved, respectively. [Birkmeyer J et al, 1999]

Volume-based policies may have disadvantageous effects, partly because volume, as a structural characteristic, is not a formal measure of quality. These policies may provide an incentive for providers whose procedural volumes are near threshold levels to increase their operative numbers by operating on patients who may not previously have been considered for surgery. Patient access to elective care in rural areas may also be impaired. There may even be detrimental implications for the quality of emergency services if providers are no longer performing elective surgery. Hospitals unable to perform specific operations may find it difficult to attract the better-qualified or better-motivated surgeons, as well as other professionals involved such as anaesthetists or nursing staff. At the other end of the volume spectrum, high volume providers may also lack the capacity to increase volume sufficiently, as most cancer procedures are currently performed at centres with low volumes. Policies advocating selective referral or minimum volume thresholds might also meet resistance from surgeons who feel that their competence in managing certain patient groups is being questioned.

Alternative policies to those based on volume for health-care quality improvement include the establishment of referral policies only to providers able to demonstrate high quality care using specific measures of outcome or to establish best practice techniques from providers with good outcomes and disseminate these to other providers using accredited teaching programmes (i.e. examining providers for clusters of good outcomes, independent of volume). [Laine C et al, 2003; Panageas K et al, 2003] These approaches, although less arbitrary than volume-based referral strategies, are also more complex and expensive and would take longer to implement and therefore may be impractical. [Bear H, 2003]

7.5 Conclusions

This review has demonstrated that on average outcomes after radical prostatectomy and cystectomy are likely to be improved if high-volume providers perform these procedures. For radical nephrectomy the evidence is less clear, with conflicting results from different studies. Nevertheless, the nature of this relationship between volume and outcome has not been adequately defined. In particular, it is not known whether this relationship is linear, whether there are single or multiple volume thresholds or how thresholds may change with time as the experience of the provider evolves. The impact of volume-based policies for radial prostatectomy and cystectomy depends on the extent to which "practice makes perfect" explains the better outcomes. Evaluation of the volume-outcome relationship for urological cancer services should be continued. Future studies should explicitly address selective referral and confounding as alternative explanations. They should preferably be performed in other health care systems than the US and use appropriate methods to adjust for disease severity and comorbidity. Ideally, longitudinal studies should be carried out whenever volume-based policies are implemented to evaluate directly their impact on outcomes.

7.6 Tables

Table 7.1: Studies analysing the effect of hospital volume on outcomes

1st Author Year published	Country of origin and time period studied	Procedure	Data Source	Case –mix adjustment score	Patient No.	Outcomes	Volume categories over study period (unless specified per year) (Number of hospitals) and outcome effect				P value†
Hu J et al 2003	US 1997-1998	RP	Claims data (Centre for Medicare and Medicaid services)	2	2292		Low <60/yr (1166)		High ≥60/yr (44)		
						In-hospital complications, adjusted OR (95% CI)	1.0		0.84 (0.59 to 1.19)		0.3
						Length of stay, PE (95% CI)	1.0		-0.42 (-0.89 to .05)		0.08
						Anastomotic stricture rates, adjusted OR (95% CI)	1.0		0.72 (0.49 to 1.04)		0.09
Begg C et al 2002	US 1992-1996	RP	SEER-Medicare linked database	3	11522		Low 1-33 (280)	Medium 34-61 (67)	High 62-107 (37)	Very high 114-252 (19)	
						30-day mortality (%)	0.5	0.5	0.5	0.5	0.8
						60-day mortality (%)	0.6	0.6	0.6	0.5	0.7
						Postoperative complications (%)	32	31	30	27	0.03
						Late urinary complications (symptoms or procedures) (%)	28	29	23	20	<0.01
						Long-term incontinence (symptoms or procedures) (%)	19	19	18	18	0.2
Ellison L et al 2000	US 1989-1995	RP	Nationwide In-patient sample	2	66 693		Low <25 (1012)	Medium 25-54 (222)	High >54 (100)		
						In-hospital mortality, adjusted OR (95% CI)	1.78 (1.2-2.7)	1.71 (1.2-2.6)	1.0		<0.001
						1995 hospital charges ($)	15 600	15 100	13 500		<0.0001
						Average length of stay (days)	7.3	-	6.1		<0.0001
Yao S et al 1999	US 1991-1994	RP	Medicare claims database	2	101604		Low ≤38 (2013)	Medium-low 39-74 (463)	Medium-high 75-140 (257)	High ≥141 (116)	
						30 day mortality, % (95%CI)	0.63 (0.53-0.73)	0.59 (0.49-0.68)	0.56 (0.47-0.66)	0.39 (0.31-0.46)	0.0015
						30 day readmission rate, % (95%CI)	5.0 (4.7-5.3)	4.5 (4.3-4.8)	4.3 (4.0-4.5)	4.1 (3.8-4.3)	0.03
						Overall complications, % (95% CI)	31.3 (30.8-31.9)	28.7 (28.2-29.3)	27.8 (27.2-28.3)	26.3 (25.8-26.9)	0.02
						Mean length of stay, days (95% CI)	8.51 (8.47-8.56)	8.18 (8.14-8.22)	7.70 (7.66-7.74)	7.81 (7.77-7.85)	0.0001

Finlayson E et al 2003	US 1995-1997	RC	Nationwide In-patient Sample	2	4937		Low <4/yr (434)	Medium 4-8/yr (114)	High >8/yr (42)			
						In-hospital mortality, %	3.6	3.0	2.5			≥0.05
Goodney P et al 2003	US 1994-1999	RC	Medicare and MEDPAR files	2	Not stated		Very low <2/yr	Low 2-3/yr	Medium 4-5/yr	High 6-11/yr	Very high >11/yr	
						Length of stay (days)	12.7	12.2	11.9	11.9	11.5	<0.05
						30-day readmission rate (%)	22.4	20.4	20.6	21.4	22.2	≥0.05
Birkmeyer J et al 2002	US 1994-1999	RC	Medicare and Nationwide In-patient sample	2	22349		Very low <2/yr (1438)	Low 2-3/yr (550)	Medium 4-5/yr (190)	High 6-11/yr (180)	Very high >11/yr (64)	
						30 day mortality, adjusted OR (95%CI)	1.0	1.00 (0.84-1.18)	0.78(0.64-0.96)	0.71 (0.58-0.86)	0.46 (0.37-0.58)	<0.001
Begg C et al 1998	US 1984-1993	RC (including pelvic exenter-ation)	SEER Medicare linked database	3	1592		Low 1-5 (259)	Medium 6-10 (53)	High ≥11 (35)			
						30 day mortality, %	3.7	3.2	1.5			0.05
Finlayson E et al 2003	US 1995-1997	RN	Nationwide In-patient Sample	2	23278		Low <15/yr (626)	Medium 15-33/yr (141)	High >33/yr (53)			
						In-hospital mortality, %	1.6	1.5	1.6			≥0.05
						In-hospital mortality, adjusted OR (95% CI) (age <65 years)	1.0		1.11 (0.40-3.09)			0.8
						In-hospital mortality, adjusted OR (95% CI) (age >65 years)	1.0		1.18 (0.75-1.87)			0.5
Birkmeyer J et al 2002	US 1994-1999	RN	Medicare and Nationwide In-patient sample	2	58990		Very low <2/yr (1916)	Low 7-12/yr (606)	Medium 13-19/yr (380)	High 20-31/yr (253)	Very high >31/yr (137)	
						30 day mortality, adjusted OR (95%CI)	1.0	0.94 (0.81-1.09)	0.83 (0.71-0.97)	0.90(0.77 -1.05)	0.80(0.68-0.95)	<0.01
Goodney P et al 2003	US 1994-1999	RN	Medicare and MEDPAR files	2	Not stated		Very low <7/yr	Low 7-12/yr	Medium 13-19/yr	High 20-31/yr	Very high >31/yr	
						Length of stay (days)	7.4	7.5	7.4	7.5	7.5	<0.05
						30-day readmission rate, %	10.7	9.7	9.4	9.4	10.3	≥0.05
Sloan F et al 1986	US 1972-1981	RN	CPHA database	2	Not stated	Correlation of increasing volume associated with increasing mortality. (Mortality categorised into low, medium and high, with mean volume of hospital provider determined.)						-

† If only significant or non-significant was stated in the text, significance or non-significance was defined at p<0.05 or ≥0.05, respectively.

Table 7.2: Studies analysing the effect of surgeon volume on outcomes

1st Author Year published	Country of origin and time period studied	Procedure	Data Source	Case –mix adjustment score	Patient number	Outcomes	Volume categories over study period (number of surgeons) and outcome effect				P value†
Hu J et al 2003	US 1997-1998	RP	Claims data (Medicare and Medicaid Services)	2	2292		Low <40/yr (1749)		High ≥40/yr (39)		
						In-hospital complications, adjusted OR (95% CI)	1.0		0.53 (0.32 to 0.89)		0.02
						Length of stay, PE (95% CI)	1.0		-0.66 (-1.26 to–0.06)		0.03
						Anastomotic stricture rates, adjusted OR (95% CI)	1.0		0.89 (0.55 to 1.44)		0.6
Begg C et al 2002	US 1992-1996	RP	SEER-Medicare linked database	3	11522		Low 1-10 (642)	Medium 11-19 (198)	High 20-32 (103)	Very high 33-121 (56)	
						30-day mortality (%)	0.4	0.5	0.5	0.5	0.7
						60-day mortality (%)	0.5	0.5	0.6	0.6	0.6
						Postoperative complications (%)	32	31	30	26	<0.001
						Late urinary complications (%)	28	26	27	20	0.001
						Long-term incontinence (%)	20	20	19	16	0.04
Karakiewicz P et al 1998	Canada 1988-1996	RP	Quebec Healthcare Plan	1	4997	30 day mortality	Surgeon volume analysed on a continuous basis "reached statistical significance, but failed to demonstrate clinically meaningful trends" in 30-day mortality rates				<0.05
Birkmeyer J et al 2003	US 1998-1999	RC	Medicare and Nationwide In-patient sample	2	Not stated		Low <2 (Number not stated)		High >3.5 (Number not stated)		
						30-day/in-patient mortality, OR (95%CI)	1.83 (1.37-2.45)		1.0		<0.001
						30-day/in-patient mortality, OR (95%CI) (After adjustment for hospital volume)	1.45 (1.03-2.04)		1.0		0.03

† If only significant or non-significant was stated in the text, significance or non-significance was defined at p<0.05 or ≥0.05, respectively.

Chapter 8

National Survey of Consultant Urological Opinion of the volume and outcome relationship in urological cancer care

8.1 Objectives

To determine minimum threshold levels of activity set by surgeons for urological cancer surgery and to relate threshold levels to current procedural volume.

8.2 Introduction

There is a growing body of evidence which demonstrates for various surgical procedures that outcomes are better in hospitals where many of such procedures are performed compared to hospitals that have less experience (see chapter 7). [Birkmeyer J et al, 2003; Begg C et al, 2002] Similarly, outcomes have also been found to be better if procedures are performed by surgeons with more experience. [Halm E et al, 2002; Hillner B, 2001; Houghton A, 1994; Hillner B et al, 2000; Birkmeyer J et al, 2002; Gandjour A, et al, 2003] Hospital or surgeon volume (the number of procedures performed in a particular hospital or by a particular surgeon) is often used as a measure of this experience. However, a relationship between volume and outcome does not seem to exist for all surgical procedures and is stronger for some procedures than for others. [Hillner B et al, 2000; Gandjour A et al, 2003; Sowden A et al, 1997]

Recently, minimum volume thresholds have been proposed in the UK for surgeons carrying out urological cancer operations. In the short term, radical surgery for prostate or bladder cancer should not be performed by surgeons who carry out fewer than five radical operations for either prostate or bladder cancer per year. In the longer term, a process of service reorganisation should occur, such that these operations should only be performed in hospitals that care for a population of at least one million people. [National Institute of Clinical Excellence, 2002]

Minimum volume thresholds should ideally define the number of cases below which the chances of a good outcome are considered to be unacceptably low or the chances of an adverse event unacceptably high. However, most studies of the volume-outcome relationship were designed to determine the existence of such a relationship rather than to establish a specific minimum volume threshold. Consequently, minimum volume thresholds can only in part be based on explicit evidence. [Birkmeyer J et al, 2003; Begg C et al, 2002; Birkmeyer J et al, 2002; Hu J et al, 2003; Ellison L et al, 2000; Yao S et al, 1999; Finlayson E et al, 2000; Goodney P et al, 2003]

In order to inform further the implementation of minimum volume thresholds for surgeons carrying out urological cancer operations, this study aimed to gauge the opinion of surgeons who perform these operations in the UK. A nationwide postal survey was carried out asking urological surgeons to provide information about their own surgical experience as well as about where they thought the minimum volume threshold should be set for radical nephrectomy, radical prostatectomy, radical cystectomy with ileal conduit or radical cystectomy with continent diversion. These four procedures were chosen because they are examples of radical urological cancer operations with different procedural complexity.

8.3 Methods

A questionnaire was sent to all 307 consultant urological surgeons who were members of the BAUS section of oncology and was piloted before full distribution (Appendix 5). The surgeons were asked to state how many of each procedure they carry out per year (including cases for the National Health Service as well as for private practice) and how many of each procedure are performed in their hospitals on average per year. They were also asked to state whether a minimum number of each procedure should be performed per year; and, if so, what this minimum number should be. Finally, consultants were asked to state their opinion on the effects of the implementation of the recently published guidance, entitled "Improving Outcomes in Urological Cancers". [National Institute of Clinical Excellence, 2002]

Three-quarters of the recipients of these questionnaires were working in non-teaching hospitals. Non-respondents were sent one reminder and in the end 212 (69%) replied. There was no appreciable difference between the percentage of respondents who worked in teaching hospitals and non-teaching hospitals (69.6% and 69.1%, respectively).

The number of procedures carried out by a surgeon, the years of experience as a consultant, and the minimum volume threshold suggested by the respondents were considered as continuous variables. As a consequence, means of these variables were compared with a t-test. Linear regression was used to calculate p-values for linear trend. All reported p-values are 2-sided and a result was considered to be statistically significant if the p-value was less than 0.05.

8.4 Results

Respondents were categorised into groups according to the number of years of experience as a consultant. On this basis, 48 (23.3%), 78 (37.9%), 41 (19.9%) and 39 (18.9%) had 1-5 years, 6-10 years, 11-15 years, and over 15 years of experience as a consultant, respectively. Nearly two-thirds of respondents had been appointed within the last ten years. Of the 212 respondents, 180 (85%) stated that they regularly performed radical nephrectomies (RN), 114 (54%) radical prostatectomies (RP), 163 (77%) radical cystectomies with ileal conduit (RCIC), and 66 (31%) radical cystectomies with continent diversion (RCCD). Considering only those respondents performing each procedure, the proportion performing over 10 procedures per year was 67% for RN, 74% for RP, 36% for RCIC, and 6% for RCCD (tables 8.1 and 8.2). The proportion of operations performed by surgeons within the private sector varied: 14% for RN, 27% for RP, 11% for RCIC, and 14% for RCCD.

The median volume (range) that surgeons said they performed per year was 12 (1-65) for radical nephrectomy (RN), 20 (1-150) for radical prostatectomy (RP), 8(1-40) for radical cystectomy with ileal conduit (RCIC) and 2(1-13) for radical cystectomy with continent diversion. Similarly, the median volume (range) that surgeons said were performed in their hospital per year was 28 (1-120), 25 (2-180), 15 (3-65) and 4 (1-20) for RN, RP, RCIC and RCCD, respectively. Annual surgeon and hospital volumes for each of these procedures were categorised into low, medium and high volume categories (table 8.2 and 8.3).

Surgeons were asked to state whether they considered themselves to be part of either a local or specialist multi-disciplinary urological cancer team (MDT). Local multidisciplinary teams serve populations of 250,000-500,000 and are usually based in cancer units at local district general hospitals. Specialist multidisciplinary teams are based in cancer centres or large hospitals and treat patients with urological cancers that are less common or require complex treatment. 92% of surgeons considered themselves part of a local MDT and 63% part of a specialist MDT. Only 2 respondents did not consider themselves part of either a specialist or a local MDT. The median (range) number of surgeons who were members of a local MDT was 3 (1-12) and of a specialist MDT was 4

(2-12). Over half of respondents considered themselves part of a local and a specialist MDT.

The majority of surgeons advocated a minimum volume threshold (see table 8.4: 77%, 89%, 86% and 84% of the surgeons, for RN, RP, RCIC and RCCD respectively). Overall, surgeons set the highest thresholds for RP and the lowest thresholds for RCCD. For example nearly half (43%) of surgeons set this at >10 procedures per year for RP, whereas only one in eight (12%) set the same threshold for RCCD. Over three-quarters of urologists believe that a minimum threshold should be set for all of these procedures, but the level of this threshold varied widely between procedures and urologists. Only considering those surgeons performing a particular procedure, we found that 13% of surgeons advocated a minimum volume threshold higher than their current volume for RN, 8% for RP, 25% for RCIC and 56% for RCCD.

Surgeons who supported the principle of setting minimum volume thresholds performed on average slightly more procedures per year than surgeons who did not, but this difference was only statistically significant for radical cystectomy with ileal conduit (table 8.5). Both groups (those who did and those who did not support setting thresholds) did not differ in the number of years that they had been working as a urological consultant for all 4 procedures (table 8.5).

Surgeons indicated higher minimum volume thresholds if they performed more procedures a year, but this association was not statistically significant for RCCD (table 8.6). There did not seem to be an association between the minimum volume threshold indicated by surgeons and the number of years that they had been working as a urological consultant surgeon for all four procedures (table 8.6). A summary analysis of comments regarding the effect of implementation of the NICE Guidance on Improving Urological Cancer Care is presented in table 8.7.

8.5 Discussion

The majority of UK urological surgeons supported the setting of a minimum volume threshold for these urological cancer procedures. The proportion of surgeons supporting thresholds ranged from about 75% for RN to about 90% for RP. Within the context of a response rate of 69% this suggests there is considerable support amongst surgeons with an interest in urological oncology for the principle of setting minimum volume thresholds. However, there was little consensus about how high these thresholds should be. It was expected that these thresholds would be lowest for the least complex procedure and highest for the most complex. Although there is no agreed definition of procedural complexity, it is generally accepted that it should reflect a combination of operation time, surgical skill, physiological impact, organisational demand for critical care and length of postoperative stay (table 8.4). Using these arbitrarily defined criteria, RCCD could be considered the most complex and RN the least complex procedure. Considering complexity in this manner does not explain the findings, because surgeons set the lowest threshold for the most complex procedure (RCCD).

An explanation for this discrepancy might be that RCCD is not only the most complex but also the least frequently performed of these four procedures. In other words, a further explanation for these findings could be that surgeons not only consider surgical complexity but also the frequency with which a procedure is performed when setting minimum volume thresholds. This can be understood because setting a minimum volume threshold for a specific procedure without considering its overall frequency could require a substantial reorganisation of existing services and the surgeons may therefore be demonstrating a degree of pragmatism. However, thresholds set on the basis of frequency rather than complexity might not necessarily provide the best outcomes for patients.

With the exception of RCCD, the majority of surgeons set threshold levels that were lower than their current volume. There are three obvious explanations for this. First, surgeons may believe that they perform sufficient numbers of cases in order to maintain both their own skills and those of the other members of the medical and nursing teams. Second, it could also reflect that these surgeons set threshold levels lower than their procedural volume in order to maintain their surgical practice, which would indicate again that a procedure's overall frequency influences the surgeons' opinion. Third, surgeons may have been imprecise in stating the number of procedures that they perform, and this might have contributed to the differences between the minimum volume thresholds they propose and their reported procedural volume.

Although the majority of surgeons set thresholds lower than their current volumes, a proportion of surgeons would need to increase their own practice in order to meet their own threshold. This suggests that there is a willingness on the part of these surgeons to change their practice, especially among those performing RCIC and RCCD.

Volume-based health policies, aimed at improving surgical outcomes, have been proposed as a result of evidence obtained from volume-outcome studies. [Berger D et al, 2003; Ihse I, 2003] Two main strategies have been used to implement these policies: either the implementation of minimum volume thresholds in order to prevent low volume hospitals or surgeons operating, or the selection of designated referral centres, thus centralising care. The latter may either be on the basis of a defined volume or on the size of a population in the catchment area of that centre.

In the context of implementation of volume-based health policies, several comments can be made. First, volume is at best a proxy for quality and increasing this volume is not a guarantee that outcomes will improve. [Berger D et al, 2003] For example, there are low volume providers with comparatively good outcomes as well as high volume providers with comparatively poor outcomes. Second, we need a better understanding of the shape of the volume-outcome relationship. The most important question is whether there is a continuous improvement in outcomes over the entire range of the observed volumes or whether above a certain volume outcomes do not improve any more with increases in volume. If the former would be the case, implementing volume-based policies should on average result in an improvement in outcomes, irrespective of current volumes. However, if the latter would be the case, increases in volume above a certain level may not result in an improvement in outcomes. Third, the uncertainty about the shape of the volume-outcome relationship explains the difficulty in determining volume thresholds that can be used to distinguish between high and low quality care as well as the observed poor agreement amongst surgeons as to the level at which minimum volume thresholds should be set. [Christian C et al, 2003] This implies that the thresholds suggested by the respondents can only be based on opinion rather than explicit evidence.

In summary, the majority of surgeons believe in the principle of setting minimum volume thresholds for urological cancer operations. Many surgeons in the UK indicated that the thresholds should be set higher than five cases per surgeon per year (the recommended NICE threshold for radical prostatectomy and radical cystectomy, until service reorganisation has occurred). The thresholds proposed by surgeons in this study appear to be influenced by current procedural volume as well as procedural complexity. By setting thresholds greater than their current volume, it is implied that some surgeons believe that their current volume is insufficient to maintain their surgical competency.

8.6 Acknowledgements

I would like to thank those surgeons who completed the questionnaire. I would also like to thank Mr David Gillatt, Consultant Urologist Southmead Hospital, Bristol, Mr Gregor McIntosh, Consultant Urologist Salisbury Healthcare Trust and Professor David Neal for their comments and suggestions during the writing of the report summarising the results of this questionnaire that was distributed to the respondents.

8.7 Tables

Table 8.1: Total number of procedures reported by surgeon performed in the NHS and privately (% of total)

(Representing a response rate of 69.1%)

	Radical nephrectomy	Radical prostatectomy	Radical cystectomy (ileal conduit)	Radical cystectomy (continent diversion)
Number of NHS procedures	2437 (86.5)	2048 (72.9)	1441 (89.4)	189 (85.9)
Number of private procedures	380 (13.5)	762 (27.1)	170 (10.6)	31 (14.1)
Total number of procedures	2817	2810	1611	220

Table 8.2: Surgeon volume categories (the number of NHS and private cases performed on average/year under the responding surgeon's care)

Procedure	Median (range)	Volume category	Number per year	Number of surgeons (%)
Radical nephrectomy	12 (1-65)	Low	1-10	60 (33.3)
		Medium	11-20	81 (45.0)
		High	>20	39 (21.7)
Radical prostatectomy	20 (1-150)	Low	1-10	30 (26.3)
		Medium	11-30	56 (49.1)
		High	>30	28 (24.6)
Radical cystectomy with ileal conduit	8 (1-40)	Low	1-5	42 (25.8)
		Medium	6-10	62 (38.0)
		High	>10	59 (36.2)
Radical cystectomy with continent diversion	2 (1-13)	Low	1-5	55 (83.3)
		Medium	6-10	7 (10.6)
		High	>10	4 (6.1)

Table 8.3: Hospital volume (number of cases performed by each respondent's hospital*)

*Some respondents may work at the same hospital.

Procedure	Median (range)	Volume category	Number/ Hospital/year	Number of surgeons (%)
Radical Nephrectomy	28 (1-120)	Low	1-10	14 (7.1)
		Medium	11-25	82 (41.8)
		High	>25	100 (51.0)
Radical Prostatectomy	25 (2-180)	Low	1-10	17 (9.8)
		Medium	11-25	76 (43.9)
		High	>25	80 (46.2)
Radical Cystectomy (ileal conduit)	15 (3-65)	Low	1-10	68 (35.4)
		Medium	11-25	86 (44.8)
		High	>25	38 (19.8)
Radical cystectomy (continent diversion)	4 (1-20)	Low	1-5	78 (75.7)
		Medium	6-10	22 (21.4)
		High	>10	3 (2.9)

Table 8.4: Minimum volume thresholds and complexity for four surgical procedures

		Radical Nephrectomy (N=200)	Radical Prostatectomy (N=202)	Radical Cystectomy With Ileal Conduit (N=201)	Radical Cystectomy with Continent diversion (N=193)
Surgeons against the setting of minimum thresholds (% respondents)		23.0	10.9	13.9	16.1
Minimum threshold/ surgeon/year (% respondents)[1]	1-5/year	20.5	13.7	28.5	44.1
	6-10/year	37.0	32.4	36.3	27.8
	11-20/year	17.5	31.9	17.6	10.4
	>20/year	2.1	11.1	3.6	1.6
Median (range) minimum threshold/year		10 (4-30)	10 (3-50)	10 (3-30)	5 (1-25)
Number (%) of surgeons suggesting a threshold > than their current volume (of those performing that procedure)		23/180 (12.7)	9/114 (7.9)	40/163 (24.5)	37/66 (56.1)
Measures of Procedural Complexity	Surgical skill required[2]	*	***	**	***
	Intensity of postoperative care[2]	**	*	***	***
	Mean length of stay (days)[3]	10·8	7·2	18·6	

[1]A number of surgeons who believed a minimum threshold should be set, did not specify a threshold level and the denominator for this percentage is therefore adjusted accordingly (4 for RN and RP, 7 for RCIC and 8 for RCCD)

[2]Ordinal scale of required surgical skill, physiological impact and requirement for high dependency or intensive care developed by authors (*least, ***most)

[3]Hospital Episode Statistics data for England 2001-2002

Table 8.5: Means of surgeon procedural volume and years of experience as a consultant for surgeons who do and do not support minimum volume thresholds

	Surgeons supporting the principle of a minimum volume threshold by procedure		P-value
	Yes	No	
Surgeon procedural volume/year			
Radical nephrectomy	14	12	0.15
Radical prostatectomy	14	9	0.29
Radical cystectomy with ileal conduit	8	5	0.03
Radical cystectomy with continent diversion	1	1	0.11
Number of years as a consultant surgeon			
Radical nephrectomy	10.1	10.8	0.52
Radical prostatectomy	9.9	11.7	0.21
Radical cystectomy with ileal conduit	9.9	11.4	0.25
Radical cystectomy with continent diversion	10.2	10.1	0.94

Table 8.6: Means of surgeon procedural volume and years of experience as a consultant for level of procedural minimum volume threshold

	Minimum volume threshold category by procedure		P-value for linear trend
	Lowest 50% of thresholds	Highest 50% of thresholds	
*Surgeon mean procedural volume/year			
Radical nephrectomy	13	17	<0.001
Radical prostatectomy	11	28	<0.001
Radical cystectomy with ileal conduit	8	11	<0.001
Radical cystectomy with continent diversion	2	4	0.34
Mean number of years as a consultant surgeon			
Radical nephrectomy	10.7	9.6	0.34
Radical prostatectomy	9.8	10.4	0.30
Radical cystectomy with ileal conduit	10.0	10.5	0.45
Radical cystectomy with continent diversion	10.1	10.3	0.06

*Considering only those surgeons performing each procedure

Table 8.7: Analysis of comments regarding the implementation of the NICE guidance

Beneficial effects of guidance		Harmful effects of guidance	
Comments	N	Comments	N
Patient factors			
Better outcomes	47	Increased travel for patients and relatives	52
Fewer complications or better management of complications	3	Increased waiting/delays in treatment	24
		Minimum numbers may mean patients bullied into opting for surgery	7
Better patient choice	1	High risk patients denied surgery	
Waiting times will fall	1	Harm majority of patients to benefit a few	2
Decreased hospital stay	1		1
Surgeon factors			
Stop surgeons doing few operations/stop rogue surgeons	25	Deskilled/demoralised DGH surgeons	50
		Competent surgeons will be prevented from operating	25
Better sub-specialist training	25	Minimum numbers are not the point; different minimum for different surgeons; outcome is the point	11
Better expertise	9		
Better cover arrangements	5	Who manages complications from the centre?	8
		Training worse	7
		Multiple site working	5
		Perfectly possible to do a large number of cases badly	4
		Newly appointed consultants have less skills already and this will worsen	3
Hospital/organisational factors			
Develop MDT working	33	Local hospitals will become deskilled/undermined	41
Better research/trial recruitment	21	Lack of funding to cope with increased work in centres	37
Better audit	18	Staff will become demoralised in DGH	27
Better pathological/radiological services	9	Problems recruiting/retaining staff in DGH	18
		Minimum numbers for hospital surgery are unrealistic	13
		Problems covering gynae. /colorectal complications	12
		Problems implementing guidance in rural areas	9
		Resources will be removed from non-cancer patients	8
		Case for centralisation not made	4
Miscellaneous factors			
More experienced nurses	14	Where is the evidence for these recommendations?	11
No harm will be caused by implementation of the guidance	7	There is no benefit to the guidance	12

Chapter 9

Volume-Outcome relationships in urological cancer care in England

9.1 Introduction

Improving the quality of care and identifying those components of quality that can influence outcomes of care are important issues both in the public and the independent healthcare sector in the UK and elsewhere. [Department of Health, 2004; Independent Healthcare Forum, 2003] Furthermore, evaluating healthcare quality on a national level can help to identify areas where quality might be suboptimal as well as provide benchmark data against which local providers may compare themselves. It is recognised, however, that there are a lack of accurate routine data on patient outcomes following surgical care. [Independent Healthcare Forum, 2003; Gill K et al, 2003] For this reason, information on the quality of surgical care in the UK is predominantly generated by relatively small ad hoc studies. Recently, a small number of large-scale national audits were initiated and sponsored by the UK Healthcare Commission to address principally government NHS priorities (e.g. cancer and coronary heart disease). [Healthcare Commission, 2003] These audits are expensive and labour-intensive. Understandably, only a limited number of surgical problems and interventions can ever be investigated in this way. In the US, a growing number of studies on the quality of surgical care are published based on administrative data, particularly using the Medicare database. [Birkmeyer J et al, 2002; Begg C et al, 2002] The Hospital Episode Statistics (HES) database contains information about all admissions to NHS hospitals and is an English equivalent of this US database that may also be used to explore the quality of surgical care.

Studies within most surgical specialties have clearly demonstrated that the number (or 'volume') of surgical procedures performed by a surgeon or at a hospital is one component that can influence the outcomes obtained. Notwithstanding this the underlying mechanism explaining this observation remains unclear, but a number of hypotheses are commonly put forward that attempt to explain why high volume has been associated with better outcomes. First, a 'practice makes perfect' phenomenon may exist that applies not only to surgical skill but also to all other aspects of healthcare provision. Second, providers with better outcomes may develop enhanced reputations and thus attract additional referrals: the 'selective referral' hypothesis. Last, high-volume providers may care for less sick or lower risk patients: the 'confounding' hypothesis.

Volume-based health policies –increasing volumes to improve outcomes – have been proposed in a number of countries partly as a result of these studies, whereby delivery of several high-risk surgical procedures is concentrated into relatively few high volume centres in an attempt to improve outcomes. [National Institute of Clinical Excellence, 2002; Leapfrog Group] A recent systematic review of volume and outcome relationships within the field of urological oncology found that all studies had been either been performed in North America or used data from between 1972 and 1999 (see chapter 7). The results of these studies may not be generalisable to other healthcare systems given their relative geographic isolation and that techniques of surgical practice have evolved over time.

The objective of this study was therefore to characterise volume and outcome relationships for radical urological cancer surgery in England using data from the HES database between 1998 and 2002. To the best of our knowledge this is the first time that such a study has been conducted on a national basis within the UK.

9.2 Methods

Database and patient identification

The HES database is an example of an English administrative database that records medical, demographic and administrative data relating to all in-patient and day surgical admissions to NHS hospitals in England. [Department of Health, 2000; Rowe R et al, 1972] It does not contain data regarding operations performed on patients within independent sector hospitals, but it does record data regarding independent sector operations performed within NHS hospitals. Data were extracted from this database for the data years 1998/1999 to 2001/2002 for all patients recorded as having undergone a radical prostatectomy (RP), radical cystectomy (RC) or radical nephrectomy (RN) (see chapter 6). Overall 20,138 patients were included.

Volume

Hospital volume was defined as the annual number of each procedure performed at each hospital averaged over the four years of the study. It is possible within the HES database to identify the consultant who is responsible for the care of each patient during an admission, but it was the opinion of the Advisory Group (appendix 1) that this identifier was not sufficiently robust to identify the surgeon who performed the operation. We therefore do not report results referring to the effect of surgeon volume on outcomes. Hospital volume was first considered as a continuous variable to ensure preservation of data relationships. To make presentation of the results more clinically meaningful, analyses were also conducted with volume considered as a categorical variable. For each of the three procedures, four volume categories were created such that approximately equal numbers of patients were placed into each volume group (very low, low, medium and high volume categories). All categorisation of volume took place prior to any statistical analysis to ensure that thresholds between volume categories were not selected on the basis of maximal effect on outcomes.

Outcomes

The primary outcome measure used in this study was in-hospital mortality. However, due to the very small number of deaths following RP we do not report any mortality analyses following this procedure. Length of hospital stay was used as a secondary outcome measure. Preliminary work with this dataset revealed that the use of crude measures of readmission as measures of surgical outcome was inappropriate as too many of the patient, surgeon and hospital factors that affect readmission remain unidentified or unmeasurable (see chapter 6). The HES database does not contain data regarding out-patient attendances and consequently we were unable to analyse procedure specific outcomes such as potency or continence rates following RP.

Statistical Analysis

Multiple logistic regression models were used to examine relationships between hospital volume and in-hospital mortality. Multiple linear regression was used to explore associations between hospital volume and length of stay. All analyses were conducted at the patient level. We adjusted for patient age (as a continuous variable), sex, ethnicity (white versus non-white), method of admission to hospital for surgery (emergency versus planned), year of surgery, and the presence or absence of coexistent comorbid conditions on the basis of the Dartmouth-Manitoba adaptation of the Charlson score, modified to exclude procedures or diagnoses occurring as a result of the reason for undergoing the urological cancer surgery (see chapter 4). [Romano P et al, 1993; Charlson M et al, 1987] Comorbidity was identified from procedural and diagnostic codes present within the index surgical admission and also from admissions occurring over the year preceding surgery, which were linked with the index admission through the use of a unique identifier that links patients across the database. Similar analyses were performed using the Deyo adaptation of the Charlson score and also using both of these adaptations of the Charlson score as continuous rather than dichotomous variables. [Deyo R et al, 1992; Deyo R, 1993] As these analyses produced similar results, we report only results using the dichotomised Dartmouth-Manitoba Charlson score. Any missing data for each variable was incorporated within a separate category within the regression models.

As outcomes for patients treated at the same hospital are more likely to be similar than the outcomes of patients treated by different hospitals, generalised estimating equations methodology was used to adjust for clustering of patients within hospitals. [Birkmeyer J et al, 2003; Panageas K et al, 2003; Fleiss J et al, 2003; Lee K et al, 2005] This increased the width of the confidence intervals but had minimal effect on the outcomes obtained. The c-statistic, recording the area under the receiver-operating curve, was used to measure the discriminative ability of the logistic models to predict in-hospital mortality and the R^2-statistic used to report the predictive value of the linear models. [Hosmer D et al, 2000] Both statistics range between 0 and 1, with 0 indicating no predictive ability and 1 indicating perfect predictive ability of the model. In other words, the statistics indicate the proportion of variation in the outcome variable that can be explained by the variables included within the model. All p-values are two-sided and a p-value of <0.05 was defined as significant. All data analysis was conducted using Stata statistical software version 8.2.

9.3 Results

Demographic characteristics, method of admission to hospital and comorbidity scores for the 20,138 patients we identified as having undergone radical urological cancer surgery between 1998-2002 are presented stratified by hospital volume quartile in table 9.1. There did not appear to be any significant differences between quartile of hospital volume and patient age or sex, except for RN where high volume hospitals tended to treat slightly younger patients, although this difference was not clinically significant. However, high volume hospitals performing RP treated a greater proportion of patients of white ethnicity. There was no consistent association between hospital volume and emergency admission (table 9.1). The only significant association between Charlson score and hospital volume was for RN where high volume hospitals treated a greater proportion of patients with comorbidity compared to without.

Volume assessed as a continuous variable

Mean (IQR) annual hospital volumes of RP, RC and RN were 15.8 (8-18.5), 11.0 (6-13.25), and 19.4 (10.5-24.5), respectively. The overall in-hospital mortality rate following RC and RN, respectively, was 4.2% and 2.0%. Increasing hospital volume was inversely related to unadjusted in-hospital mortality for RC and RN, although this was only statistically significant for RC (table 2). Following adjustment for case mix and clustering at the hospital level, increasing hospital volume was still associated with a trend towards decreasing mortality for both procedures, and this remained significant for RC. The c-statistics for these models were 0.66 and 0.74 for RC and RN, respectively.

The overall mean length of stay following RP, RC and RN, respectively, was 7.9 days, 18.8 days and 11.0 days. Increasing hospital volume was related to a shorter unadjusted length of stay for RP and RN, but these effects were no longer statistically significant following adjustment for casemix and clustering at the hospital level (table 9.2). In contrast, following RC increasing hospital volume was associated with a significantly longer unadjusted length of stay, but again this effect was no longer significant following adjustment for casemix and clustering (table 9.2).

Volume assessed as a categorical variable

Observed, unadjusted and adjusted hospital mortality rates following RC and RN are presented by quartile of hospital volume in table 9.3. For RC, very low volume hospitals had almost twice the unadjusted odds of hospital mortality compared to high volume hospitals. Although this effect diminished slightly following adjustment for casemix and clustering, it remained statistically significant. For RN, hospital volume category was not significantly predictive of in-hospital mortality (table 9.3).

Unadjusted and adjusted length of stay after RP was significantly longer in very low volume hospitals compared with high volume hospitals (table 9.4). For RC, unadjusted length of stay was significantly longer in high compared to very low volume hospitals, but following adjustment this effect was no longer significant. For RN, length of stay was longest in very low volume hospitals, but the difference between very low and high volume hospitals (0.3 days) was not clinically significant (table 9.4). Following adjustment, this effect also became statistically non-significant.

9.4 Discussion

Hospital volume appears to be inversely related to in-hospital mortality following RC. No similar effect was demonstrable following RN. We could not identify any effect of hospital volume on length of stay following RC or RN, but dependent on the method of analysis, length of stay after RP was slightly shorter in high volume hospitals.

The results of this study suggest that it is not possible to generalise the effect of hospital volume on outcomes following one procedure to another procedure. For example, although length of stay was longer in very low volume hospitals following RP, this effect was not significant for RN, and for RC length of stay was actually higher in the highest volume hospitals.

The magnitude of the effect of hospital volume is therefore dependent on the surgical procedure and also on the surgical outcome under study. This effect tended to fall following adjustment for casemix and clustering. Differing methods of analysing the effect of volume also produced different effects on outcome. Our results are consistent with the body of previous evidence, predominantly from the US and summarised in a recent systematic review, which also found that outcomes following RP and RC tend to improve with increasing hospital or surgeon volume. For RN, however, previous studies produced conflicting results (see chapter 7). This may be because RN tends to be a less complex procedure, and therefore lends credence to the 'practice makes perfect' hypothesis. Although we did not find systematic differences between comorbidity according to volume for RC and RP, we did observe that high volume hospitals were more likely to treat patients with compared to without comorbidity for RN than lower volume hospitals. Consequently, the observed relationships between volume and outcome may in reality be stronger than our results suggest, given that this observation could confound our results. Moreover, we were unable to make adjustment for the effect of surgical approach (e.g. open or laparoscopic), or method of reconstruction (e.g. ileal conduit or continent diversion after RC). It might be expected that higher volume hospitals might perform more complex reconstructive or laparoscopic procedures than lower volume providers.

Study limitations

There are a number of limitations associated with this study that relate to problems bedevilling sources of administrative data such as HES, in part because the data were collected for reasons other than answering specific research questions. First, this study was unable to make any adjustment for disease severity or stage, and was limited in its ability to adjust for comorbid disease. However, previous work has demonstrated that Charlson comorbidity scores derived from this ICD-10 database perform similarly to those derived in previous studies from ICD-9 databases and has shown that administrative data are able to identify the presence of comorbid disease to an extent necessary to control for differences in casemix between patient populations (see chapter 4). It could be argued that adjustment for comorbidity is of greater importance than adjustment for disease severity as the latter is more likely to affect longer-term outcomes such as disease-free survival, rather than the shorter-term outcomes used in the present study. What is more, previous work has demonstrated that adjusting for comorbidity does not seem to have a large additional impact compared to adjusting for age and sex alone (see chapter 4). [Cleves M et al, 1997; Ghali W et al, 1996]

Second, the outcome measures in this study were limited to in-hospital mortality and length of stay, although this is also consistent with much of the volume-outcome literature. [Urbach D, 2004] In the future in similar studies, linkage with mortality data from the UK Office of National Statistics should permit the use of other outcome measures such as 30-day mortality and 5-year survival. [Gill L et al; Office of National Statistics] We were unable to study the effect of volume on quality of life outcomes or of disease specific outcomes such as potency or continence rates after RP – outcomes that arguably may be of more importance to patients.

Third, our identification of index cases and thus our measures of surgical activity may be imprecise. However, the procedures and the diseases considered within this study all represent major events that we believe are unlikely to suffer from widespread coding inaccuracy. There are concerns regarding the ability of the HES database to identify accurately the operating surgeon. This problem has been recognised and from 2004, there will be a separate field within the database that identifies both the operating surgeon and anaesthetist. In the future the BAUS Section of Oncology Complex Operations database should provide data against which the measures of hospital volume in the present study can be validated. [Directory of Clinical Databases]

Last, although volume is easily measurable and definable, it is only a proxy for other hospital and surgeon factors that may on average be associated with improved outcomes. [Berger D et al, 2003; Begg C et al, 2003; Christian C et al, 2003; Epstein A 2002] These include hospital type (e.g. teaching versus district general hospital), surgeon type (e.g. urologist versus general surgeon), and the presence or absence or experience of staff within intensive care facilities. We were unable to include adjustments for these factors. Nevertheless, a strength of the HES database is that it has almost complete national in-patient coverage. This compares favourably with similar US studies of the Medicare database that have to extrapolate measures of volume to include patients under the age of 65 years. [Birkmeyer J et al, 2002; Birkmeyer J et al , 2003; Goodney P et al, 2003]

Policy implications

Our results add further weight to the body of evidence that demonstrates an association between procedural volume and the outcomes attained following RC. However, it is clear from our results and from those of others that the magnitude of this effect varies markedly by procedure and by the outcome under study. However, observing a volume-outcome relationship and then translating this into policy is fraught with difficulty, partly because high volume is no guarantee of better quality. There are for instance, examples of high volume providers with relatively poor outcomes, together with examples of low volume providers with relatively good outcomes. Volume-based policies require answers to a number of questions. Firstly, should volume be set at the surgeon level or the hospital level? Secondly, should account be taken of a surgeon's or a hospital's previous experience? For example, should thresholds be different for an individual just starting independent practice compared to a surgeon with years of experience? Finally, are the results of volume-outcome studies explained through poor performance at the lower volume end of the spectrum or through a high level of performance at the higher volume end of the spectrum? If it were the low volume providers who are performing poorly, one strategy would be to increase resources at low volume providers, thus improving access to care, preventing erosion of local emergency care, and reducing the burden on the continuum of care. However, this would diminish the ability to measure outcomes more precisely through the high volumes generated through centralising care.

Future work

These results illustrate the need for national prospective clinical databases that record data on disease severity and long-term outcomes, which in part can be validated by sources of administrative data such as HES and vice versa. In the meantime, proposed enhancements to the HES database in the number of available diagnosis and procedural fields, together with improvements in the ability to identify the operating surgeon will improve the utility of this database. The next challenge is to identify characteristics of both centres and surgeons associated with good outcomes so that these practices might be used in both selection and training and also emulated by others to improve outcomes even further.

Conclusions

Hospital volume appears to be inversely related to in-hospital mortality following RC. No similar effect was demonstrable following RN. We could not identify any effect of hospital volume on length of stay following RC or RN, but dependent on the method of analysis, length of stay after RP was slightly shorter in high volume hospitals. Data from this study provides limited evidence in support of volume-based health policies for RC, but minimal support for such policies relating to RN or RP. However, the study was hampered by the inability to study quality of life outcomes and to adjust for the effect of surgeon volume on outcomes.

9.5 Tables

Table 9.1: Characteristics by quartiles of hospital volume of 20138 radical urological cancer surgery patients

Procedure	Hospital volume				P value for trend
	Very Low	Low	Medium	High	
Radical Prostatectomy					
Number of patients	1212	1327	1073	1174	-
Number of hospitals	100	30	16	11	-
Number of patients per hospital (range)	1-8	9-14	15-19	>19	-
Mean age (years)	62.5	62.7	62.7	63.5	0.544
White race, number (%)	816 (92.4)	788 (90.1)	591 (94.9)	803 (94.3)	0.014
Emergency admission, number (%)	5 (0.4)	7 (0.5)	5 (0.5)	7 (0.6)	0.592
Charlson score ≥1, number (%)	164 (13.5)	199 (15.0)	136 (12.7)	177 (15.1)	0.603
Radical Cystectomy					
Number of patients	1300	1427	952	1292	-
Number of hospitals	115	46	21	17	-
Number of patients hospital (range)	1-6	7-10	11-13	>13	-
Mean age (years)	66.5	66.7	66.4	63.3	0.882
White race, number (%)	929 (96.2)	1013 (98.2)	736 (98.1)	857 (97.2)	0.212
Female sex, number (%)	317 (24.4)	335 (23.5)	239 (25.1)	310 (24.0)	0.959
Emergency admission, number (%)	72 (5.5)	86 (6.0)	45 (4.7)	75 (5.8)	0.913
Charlson score ≥1, number (%)	693 (53.3)	690 (48.4)	504 (52.9)	629 (48.7)	0.117
Radical Nephrectomy					
Number of patients	2827	2712	2346	2496	-
Number of hospitals	126	50	29	18	-
Number of patients per hospital (range)	1-11	12-16	16-25	>25	-
Mean age (years)	64.3	64.0	64.3	63.4	0.031
White race, number (%)	1828 (95.3)	1720 (96.8)	1591 (96.3)	1458 (96.2)	0.272
Female sex, number (%)	1067 (37.8)	1013 (37.4)	814 (34.7)	920 (36.9)	0.201
Emergency admission, number (%)	273 (9.7)	268 (9.9)	223 (9.5)	209 (8.4)	0.100
Charlson score ≥1, number (%)	1058 (37.4)	993 (36.7)	877 (37.4)	1029 (41.2)	0.005

Table 9.2: Observed and adjusted in-hospital mortality rates and length of stay by hospital volume as continuous variables*

Procedure	Hospital volume		
In-hospital mortality	Odds ratio per unit increase in volume (95% CI)	P value	C statistic
Radical Cystectomy			
Unadjusted odds ratio	0.961 (0.939-0.983)	0.001	0.58
Adjusted odds ratio*	0.963 (0.941-0.985)	0.001	0.66
Adjusted odds ratio for clustering†	0.963 (0.935-0.991)	0.011	0.66
Radical Nephrectomy			
Unadjusted odds ratio	0.995 (0.984-1.006)	0.366	0.50
Adjusted odds ratio*	0.996 (0.985-1.007)	0.467	0.74
Adjusted odds ratio for clustering†	0.996 (0.980-1.012)	0.616	0.74
Length of stay	Coefficient (95% CI)	P value	R^2 statistic
Radical Prostatectomy			
Unadjusted coefficient	-0.018 (-0.029 to -0.006)	0.003	0.0019
Adjusted Coefficient*	-0.017 (-0.029 to -0.006)	0.003	0.0271
Adjusted Coefficient with clustering†	-0.017 (-0.047 to -0.013)	0.256	0.0271
Radical Cystectomy			
Unadjusted coefficient	0.062 (0.012 to 0.113)	0.015	0.0012
Adjusted Coefficient*	0.069 (0.019 to 0.119)	0.017	0.0304
Adjusted Coefficient with clustering†	0.069 (-0.020 to 0.157)	0.127	0.0304
Radical Nephrectomy			
Unadjusted coefficient	-0.001 (-0.014 to 0.012)	0.906	0.0000
Adjusted Coefficient*	0.005 (-0.007 to 0.017)	0.399	0.1107
Adjusted Coefficient with clustering†	0.005 (-0.025 to 0.035)	0.729	0.1107

* Odds ratios and coefficients according to hospital volume expressed as a continuous variable were adjusted for age, sex, ethnicity, method of admission (emergency vs. planned), year of surgery, and Charlson score.
†Odds ratios and coefficients were further adjusted for clustering at the hospital level.

Table 9.3: Observed, unadjusted and adjusted in-hospital mortality rates by quartile of hospital volume

Procedure	Hospital volume			
	Very Low	Low	Medium	High
Radical Prostatectomy				
Observed mortality rate (%)	2 (0.2)	4 (0.3)	0 (0.0)	0 (0.0)
Unadjusted OR (95% CI)	-	-	-	-
Adjusted OR (95% CI)*	-	-	-	-
Adjusted OR for clustering (95% CI) †	-	-	-	-
Radical Cystectomy				
Observed mortality rate (%)	64 (4.9)	77 (5.4)	30 (3.2)	36 (2.8)
Unadjusted OR (95% CI)	1.0	1.10 (0.78-1.55)	0.63 (0.40-0.98)	0.55 (0.37-0.84)
Adjusted OR (95% CI)*	1.0	1.15 (0.81-1.62)	0.64 (0.41-1.00)	0.57 (0.38-0.87)
Adjusted OR for clustering (95% CI) †	1.0	1.15 (0.77-1.72)	0.64 (0.38-1.08)	0.57 (0.35-0.94)
Radical Nephrectomy				
Observed mortality rate (%)	57 (2.0)	50 (1.8)	52 (2.2)	51 (2.0)
Unadjusted OR (95% CI)	1.0	0.91 (0.62-1.34)	1.10 (0.75-1.61)	1.01 (0.69-1.48)
Adjusted OR (95% CI)*	1.0	0.95 (0.65-1.40)	1.13 (0.77-1.66)	1.07 (0.73-1.58)
Adjusted OR for clustering (95% CI) †	1.0	0.95 (0.64-1.42)	1.13 (0.70-1.82)	1.07 (0.63-1.83)

OR – odds ratio

*Adjusted for age, sex, ethnicity, method of admission, year of surgery, and Charlson score

† Further adjustment for clustering at the hospital level

Table 9.4: Multivariate linear regression analysis for length of stay by procedure by quartile of hospital volume

Procedure	Hospital volume				P value for trend
	Very Low	Low	Medium	High	
Radical Prostatectomy					
Mean length of stay (days)	8.5	7.7	8.1	7.3	<0.001
Adjusted coefficient (95% CI)*	1.14 (0.39 to 1.89)	0.46 (-0.32 to 1.24)	0.81 (-0.17 to 1.78)	0.0	0.013
Radical Cystectomy					
Mean length of stay (days)	18.5	18.6	18.3	19.6	<0.001
Adjusted coefficient (95% CI)*	-1.13 (-3.67 to 1.40)	-0.98 (-3.52 to 1.55)	-1.15 (-4.38 to 2.08)	0.0	0.420
Radical Nephrectomy					
Mean length of stay (days)	11.4	11.2	10.1	11.1	<0.001
Adjusted coefficient (95% CI)*	0.05 (-1.00 to 1.09)	-0.02 (-1.09 to 1.05)	-1.1 (-2.29 to 0.06)	0.0	0.460

*Adjusted for age, sex, ethnicity, method of admission, year of surgery, Charlson score and clustering.
Coefficient represents the change in days of the length of stay for each category of hospital volume with reference to the high hospital volume category.

Section 5

General Discussion and Policy Implications

Chapter 10

General Discussion

This chapter is divided into four subsections. Firstly, a brief summary of the thesis is presented. The limitations of this work have been presented within the discussion sections of each of the relevant chapters, and for this reason they are not repeated here. Secondly, the setting and effects of implementation of volume and outcome policies are discussed. Thirdly, a number of limitations of the HES database are presented, together with proposals to improve the database, which would make both conducting similar studies in the future easier, and also allow these studies to be taken further. Finally, suggestions for future research are discussed, including the need for collaborative work with national clinical databases as part of a cross-validation programme of both the HES data and the clinical databases.

10.1 Summary of thesis

Section one

Section one was an introduction to and a general overview of this thesis. In chapter one the objectives of this thesis were introduced, together with a description of how this programme of work commenced. Background information was presented that related to the use of administrative data in measuring the quality of surgical care bothin the US and in the UK. Chapter two went on to briefly summarise the epidemiology and treatment for the three urological cancers considered in this thesis – cancer of the prostate, bladder and kidney – for non-urological readers of this thesis.

Section two

Chapter three introduced the concept of routinely collected administrative databases and the HES database in particular, and also discussed the practicalities of obtaining data extracts from the database. In this section a study was presented that described the development of a casemix adjustment score that utilised information on disease comorbidities obtained in part from hospital admissions over the year preceding admission for surgery. This score was used in subsequent chapters of the thesis and was the first time that a validated casemix adjustment score has been developed that allows for a degree of risk adjustment within the HES database. Charlson Deyo and Dartmouth-Manitoba scores were derived from the ICD-10 HES data and were found to represent a valid approach to adjust for comorbidity. Both Charlson Deyo and Dartmouth-Manitoba scores performed very similarly in risk models predicting hospital mortality following urological cancer surgery. However, within the HES databse, adjusting for comorbidity did not seem to have a large additional impact when compared to adjusting for age and sex alone. The reasons for this are complex but may relate to data quality issues within administrative databases in general. Errors can stem not only from inaccurate patient records, poor abstractation of the clinical record, or from inaccurate coding, but also from a limited ability to adjust for disease severity and to distinguish between complications of care and prexisting comorbidities.

Section three

The first chapter in this section presented a descriptive analysis of the practice and outcomes for radical urological cancer surgery in England on the basis of data extracted from the HES database. Despite inherent limitations of the data, the consistency of the observed demographic trends over time within this study and the face validity of the observed associations between patient demographics and outcomes support the validity of the reported results. Within chapter six, the use of emergency readmissions as a measure of surgical outcome in addition to the more easily identifiable outcomes of in-hospital mortality and length of hospital stay was explored. Analysis of HES data revealed that hospitals performing RP, RC and RN should plan for about one fifth, two fifths and one quarter of their patients, respectively, to undergo emergency readmission within a year of surgery. However, readmissions are the result of a complex set of interactions that depend on a number of inputs. In order to use emergency readmission rates as a measure of surgical outcome, future work is required to examine the hospital and surgeon characteristics that effect readmissions, together with patient factors such as disease severity and access to primary care facilities.

Section four

The final section of the thesis discussed volume and outcome relationships in radical urological cancer surgery. Firstly, chapter seven presented a systematic review of the volume and outcome literature for these three urological cancer procedures. This review demonstrated that on average, outcomes after radical prostatectomy and cystectomy are likely to be improved if high-volume providers perform these procedures. For radical nephrectomy the evidence was less clear, with conflicting results from different studies. Nevertheless, the nature of this relationship between volume and outcome had not been adequately defined. In particular it is not known whether this relationship is linear, whether there are single or multiple volume thresholds or how thresholds may change with time as the experience of the provider evolves. The impact of volume-based policies for prostatectomy and cystectomy depends on the extent to which 'practice makes perfect' explains the better outcomes. Evaluation of the volume-outcome relationship for urological cancer services should be continued. There were also a number of limitations within the included studies and these were discussed. Future studies should preferably be performed in health care systems other than the US and use appropriate methods to adjust for disease severity and comorbidity.

Secondly, chapter eight described the results of a national survey of consultant urological opinion relating to volume and outcome relationships in urological cancer care, and in particular where volume thresholds could be set for these operations (see appendix 5). The majority of UK urological surgeons supported the setting of a minimum volume threshold for these urological cancer procedures. The proportion of surgeons supporting thresholds ranged from about 75% for RN to about 90% for RP, but there was quite wide opinion as to where these thresholds should be set. The thresholds proposed by surgeons in the study appeared to be influenced by current procedural volume as well as procedural complexity.

Finally, chapter nine utilised data and methodology presented in previous chapters to describe volume and outcome relationships for urological cancer surgery in England on the basis of the HES data. In summary, hospital volume appeared to be inversely related to in-hospital mortality following RC. No similar effect was demonstrable following RN. No effect of hospital volume on length of stay following RC or RN could be identified, but dependent on the method of analysis, length of stay after RP was slightly shorter in high volume hospitals. Data from this study therefore provides some evidence in support of volume-based health policies for RC, but less support for such policies relating to RN or RP. However, the magnitude of these effects was procedural dependent and tended to fall following adjustment for patient demographics and comorbidity. Differing methods of analysing the effect of volume produced different effects on outcome. These results are consistent with much of the volume and outcome literature, but clearly also dependent upon the completeness and accuracy of the routinely collected HES data. It is currently not possible to study quality of life outcomes using most administrative databases, which for procedures such as RP are arguably of the most importance for patients.

The following subsection in this chapter puts some of the results from chapter nine and also from other volume and outcome studies into the context of setting and implementing volume-based policies.

10.2 Setting and implementing volume-based policies

Work from this thesis has illustrated the growing number of studies that show outcomes are likely to improve for complex urological cancer surgical procedures if these procedures are performed either within high volume hospitals or by high volume surgeons (see chapter 7). Partly as a consequence of these studies, the UK National Institute of Clinical Excellence (NICE) recommended that complex urological cancer surgery be centralised into centres serving a population of at least one million. [National Institute of Clinical Excellence, 2002] Based on this population, this should result in at least 50 radical operations for prostate and bladder cancer being performed per centre per year. The number of clinicians involved in treating these patients in the centres will determine whether this also provides relatively high volume at the surgeon level. Volume-based policies such as that advocated by NICE are not without controversy however, as high volume can only be a proxy for other factors that improve healthcare outcomes. [Berger D et al, 2003; Birkmeyer J, 2000]

There exist three explanations of how volume and outcome may be linked (see chapter seven). [Birkmeyer J, 2000] The first and most intuitive is the 'practice makes perfect' explanation. This postulates that improvements in outcome result from the enhanced performance gained through increased practice and experience. This effect may act in a number of areas. For example, at the individual level a surgeon may be able to reduce operative time and possibly blood loss. At the structural level, a hospital may be better able to implement evidence-based guidelines and enhance multi-disciplinary team working. The second of these explanations has been described as the 'selective referral' explanation. Hospitals or surgeons who have good outcomes may attract additional referrals and thus increase their volume. [Ihse I, 2003] This is almost certainly the case in certain centres in the USA, for example in those that attract an international clientele. The third explanation proposes that observed effects between volume and outcome might be explained by 'confounding'. In other words, a difference in casemix (incorporating both comorbidity and disease severity) may exist such that high volume hospitals or surgeons care for lower risk patients.

Most evidence on the volume-outcome relationship originates from studies performed in the US. The validity of this evidence would be stronger if more data from other countries and healthcare systems were available. The healthcare system in the UK differs from that in the US in that most British patients currently have little control over where they receive their surgical treatment and even less by whom the surgical procedure is performed. If a volume-outcome relationship was to be found as consistently in the UK as in the US, this would mitigate against the selective referral explanation. Confounding is less likely to play a significant role as most studies that adjust for confounding still demonstrate a positive effect between volume and outcome. [Birkmeyer J, 2000] Moreover, the incorporation of the comorbidity index developed in chapter four into the statistical models exploring volume-outcome relationships in chapter nine showed a similar effect was observed within the English HES data. Nevertheless, the implementation of volume-based policies aimed at improving surgical outcomes implies that policy-makers have embraced the dominance of the 'practice makes perfect' explanation.

Based on available evidence, it is likely that implementing a volume-based policy for complex urological cancer surgery will, on average, result in improved outcomes (see chapter seven). In addition, there may be other desirable by-products such as more intensive training opportunities and easier recruitment of patients into trials. The large number of cases at high volume centres should also ensure greater statistical precision surrounding reported patient outcomes.

However, by their nature volume-based health policies need to be applied to an entire healthcare system in order to have the maximum desired effect. This has a number of implications. First, low volume providers with good outcomes will be lost to the healthcare system if they are either unwilling or unable to practise within high-volume centres. Second, there may also be an incentive to increase volumes through operating on patients who may not previously have been considered for surgery. Third, newly created high volume providers may not necessarily produce better outcomes than the low volume providers that preceded them. [Shahian D et al, 2003] Fourth, the addition of another layer to secondary care may put pressure on effective communication and adversely affect the continuum of care. [Haggerty J et al, 2003] Finally, some patients may have a preference for locally based care regardless of the local outcomes.

Whilst acknowledging these methodological problems, if it is taken as given that outcomes improve with increasing volumes, uncertainties remain in how to translate this effect into policy. For instance, should low volume providers be excluded from the healthcare system or should referral only take place to those providers with high volume? Moreover, at what level should volume thresholds be set? These thresholds define the minimum number of cases a provider should perform in order to be classified as 'high' or 'low' volume. Although studies have tried to identify these thresholds, considerable variation in methodology and threshold levels have been encountered. [Shahian D et al, 2003; Christian C et al, 2003] What is more, should these thresholds be set at the surgeon level, at the hospital level or both? Should account be taken of experience in related fields? These questions illustrate the need for continuing research to define the shape of the volume and outcome curve for differing categories of providers. The work presented in chapter eight illustrated that although most surgeons believed in the principle of setting minimum volume thresholds for urological cancer operations, there was also considerable variation between surgeons as to where these thresholds should be set.

Moving beyond volume

Other process or structural characteristics of the health care process, more difficult to measure or define than volume, are more likely to predict outcome, and therefore there is a need for more direct measures than volume to determine quality in healthcare. The policy implications for this are unclear, as the characteristics of high volume providers with good outcomes have not been defined and therefore cannot be easily replicated by other providers. Nevertheless, policymaking is not based purely on evidence, and a lack of evidence is not in itself a justification for inertia in attempts to improve health quality. Policymakers take into consideration other aspects when developing policy, including financial, social, electoral and strategic development factors and this is particularly so when there is a lack of agreement over the evidence or when it is lacking [Black N, 2001].

Previous work has shown that simply by measuring outcomes and feeding back performance can result in dramatic reductions in morbidity and mortality rates. [UK and Ireland National Liver Transplant Audit, 2002] More attention needs to be focussed on patient centred outcomes, whereby instruments are developed that measure health related quality of life efficiently and inexpensively, especially for surgical procedures such as radical prostatectomy where the more traditional outcomes such as mortality occur rarely, and length of stay vary minimally between providers. [Birkmeyer J et al, 2004; Baxter N, 2005]

Following implementation of volume-based policies, and within the new configuration, the next challenge is to identify characteristics of both centres and surgeons associated with good outcomes so that these practices might be used in both selection and training and also emulated by others to improve outcomes even further. [Shahian D et al, 2003; Begg C et al, 2003] This will continue to improve the quality of care whilst the answer to the question of 'how many is enough?' remains so elusive.

10.3 Limitations and areas for improvement within the HES database

During the process of conducting this research, a number of practical limitations within the HES database have been encountered. In particular, one of the major limitations was the ability to study only in-hospital mortality (see chapters 6 and 9). However, the linkage of HES with ONS data to allow indefinite tracking of mortality, such as achieved with the central cardiac surgery audit database, will help to solve this problem, greatly strengthening this database. [Keogh B et al, 2005]

A further limitation that was found with the HES database was with the utility of the consultant identifier field. There is fairly widespread cynicism amongst consultants of the uses to which this identifier can be put. In particular, it was also the opinion of the advisory group to this project that the operating surgeon and the consultant coded as responsible for a patient's care might not necessarily be the same individual. Furthermore, in some hospitals the lead consultant in a consultant team may be recorded as responsible for a patient's care. It was therefore decided not to make use of the consultant identifier in this project. Consequently, this prevented investigation of the effect of surgeon volume on outcomes after surgery on the basis of HES data. However, plans to create new data fields that specifically identify the operating surgeon and also the anaesthetist will help to increase the confidence amongst surgeons in the ability of HES to identify accurately surgeon activity. [Bloor K et al, 2004] Furthermore, clinical performance monitoring together with payment by results will force clinicians to take a more active role in data collection: although some clinicians may consider this a diversion of effort towards irrelevant responsibilities.

Attempting to stratify comorbid risk amongst patients undergoing surgery represents a major component of many studies reporting surgical activities and outcomes. Work from this thesis has demonstrated that from using the diagnosis and procedure codes present within the HES database it is possible to generate a valid comorbidity score. The utility of this score needs to be demonstrated in further studies that include different groups of both surgical and medical patients. What is more, the future addition of a HES data field describing the American Society of Anaesthesiologists (ASA) score is a welcome enhancement to the HES database that will give an estimate of surgical risk at the time of surgery.

Finally, the data acquisition process from the Department of Health was quite cumbersome: in part because of the data confidentiality issues that bedevil working with both clinical and administrative databases. The Clinical Effectiveness Unit at the Royal College of Surgeons of England has recently been granted direct on-line access to the HES database, which has already shortened the timescale of a number of related projects being conducted in the Unit.

10.4 Future Directions

Data quality and validation

Data quality within HES represents is an important issue. Hospital Episode Statistics were used in this study because of their relative availability and lengthy period of data collection. Increasing numbers of studies are now using HES data to report both national trends and to scrutinise hospital or surgeon performance. [Aylin P et al, 2004; Poloniecki J et al, 2004; Reid P et al, 2005] These studies, and others, support the use of HES data for such purposes, and have also suggested that the completeness of HES data is improving. However, there is clearly a necessity for further validation of HES data. The work from this project has generated collaboration with national clinical databases of the Sections of Endourology and Oncology of the British Association of Urological Surgeons that aims to identify inconsistencies between these clinical datasets and HES. [Directory of Clinical Databases, 2004] Hopefully, this work will encourage similar efforts elsewhere in order that the full potential of the HES database may be realised. In time clinical and administrative databases could function as one, with each acting as a source of validation and corroboration of the other.

The CEU at the Royal College of Surgeons of England is also planning parallel work whereby data that the CEU has previously collected through a number of national surgical audits (National Joint Registry, National Prostatectomy Audit and National Prospective Tonsillectomy Audit) will be directly compared at a hospital level with HES data to assess completeness. [Emberton M et al, 1995; National Prospective Tonsillectomy Audit, 2004] The CEU also proposes –dependent on funding – to conduct a data validation exercise that concentrates on the comorbidity index developed in chapter four. By doing so it will also evaluate the accuracy and completeness of HES data. The first part of this proposal is to use data from within the HES database to evaluate both convergent validity (e.g. associations between comorbidity and patients' age) and also to evaluate discriminant validity (e.g. the ability to discriminate between patients with 'good' and those with 'bad' outcomes using comorbidity data). The second part of the proposal is to seek a direct validation with the medical records of 500 patients (25 patients in 20 hospitals, both randomly selected).

10.5 Concluding comments

Information on the risks of major surgery is essential for any patient who is considering undergoing major surgery. Patients are often presented with optimistic data from highly selected case series. This thesis has clearly shown that outcomes reported from such series are often considerably better than those generated from a national level (see chapter five). In particular, population based operative mortality following major surgery is considerably higher than that typically reported in case series and trials. For example, the present work has demonstrated that the national in-hospital mortality rate following radical nephrectomy over the period of study was 2.1%, over twice that reported in a number of large case series (<1%).

Although this study has identified that volume can influence health care outcomes, the relationships between volume and outcome are complex. They are different for different surgical procedures and separate studies from differing countries are reporting inconsistent results. Other process or structural characteristics of the health care process, more difficult to measure or define than volume, are more likely to predict outcome, and therefore there is a need for more direct measures than volume to determine quality in healthcare.

HES data are the best available when it comes to studying national trends in hospital performance but are not without some defects. [Bloor K et al, 2004] Following the Shipman inquiry and the formal implementation of the General Medical Council revalidation process, there is likely to be organised and formal supervision of activity data. However, measuring activity alone may well be inadequate and easily obtainable existing outcomes such as mortality, length of stay or readmission rates will need to be complemented with quality of life measures. [Maynard A, 2005]

Routinely collected data such as that from the HES database will never be perfect, and perhaps this should simply be accepted. However, it is important to try to achieve the highest quality within the constraints of limited resources. Samuel Johnson, a writer who lived in London in the 18th century said "it is reasonable to have perfection in the eye that we may always advance towards it, though we know it can never be reached". This is as true today as it was 250 years ago.

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Appendices

Appendix 1

Practice and outcomes for radical urological cancer surgery in England: a study based on Hospital Episode Statistics

Members of the advisory group

Mr Mark Emberton (ME) (Chairman)	Senior Lecturer in Urological Oncology and Honorary Consultant Urological Surgeon Institute of Urology and Nephrology, London Clinical Director, Clinical Effectivenss Unit, the Royal College of Surgeons of England
Mr Martin Nuttall (MN)	Urological Research Fellow The Royal College of Surgeons of England
Dr Jan van der Meulen. (JvdM)	Senior Lecturer in Epidemiology London School of Hygiene and Tropical Medicine Director, Clinical Effectivenss Unit, the Royal College of Surgeons of England
Mrs Linda Shurlock (LS)	Senior Section Head Hospital Episode Statistics, Department of Health
Mr Gregor McIntosh (GM)	Section of Oncology British Association of Urological Surgeons Consultant Urologist, Salisbury Healthcare NHS Trust, Salisbury
Mr David Gillatt (DG)	Section of Oncology British Association of Urological Surgeons Consultant Urologist, Southmead Hospital, Bristol
Dr Nirree Phillips (NP)	Research Fellow in Epidemiology London School of Hygiene and Tropical Medicine
Dr James Lewsey (JL)	Lecturer in Medical Statistics London School of Hygiene and Tropical Medicine

Appendix 2

Translation of Deyo and Dartmouth-Manitoba ICD-9-CM codes into ICD-10 and OPCS-4 codes[Romano 1993]

Diagnostic category	Deyo code	Dartmouth-Manitoba code	Deyo diagnostic code translation	Deyo Procedure Codes Translation	Dartmouth-Manitoba diagnostic code translation	Dartmouth-Manitoba Procedure codes translation
Myocardial infarction	410.xx, 412*	410.xx, 412*	I21, I22, I236, I240, I513, I252, I252*‡	-	I21, I22, I236, I240, I513, I252 I252*‡	-
Congestive cardiac failure	428.x	420.01,402.11,402.91,425 x,428x,429.3, 404.01,404.03, 404.11, 404.13,404.91,404.93	I50, I469	-	I11, , I13, I412, I42, I43, I469, I50, I517, I528, I980, I981, I988	-
Peripheral vascular disease	441.x*,443.9*,785.4*,V4 3.4*,38.48(P)	440.x*, 441.x*, 442.x*, 443.1-443.9*, 447.1*, 785.4*, 38.13-38.14(P)*, 36.16(P)*, 38.18(P)*, 38.33-38.34(P)*, 38.36(P)*, 38.38(P)*, 38.43-38.44(P)*, 38.46(P)*, 38.48(P)*, 39.22-39.26(P)*, 39.29(P)*	I71, I790, I739, R02, Z951,Z955, Z958, Z959 (all *)‡	L56, L57 L58, L59, L62, L653	I70, I71, I790, I792, I72, I770, I731, I738, I739, I771, R02‡	L373, L374 L38, L371 L251, L252 L16, L18, L19, L20, L21, L22, L23, L651, L254 L414, L453, L454, L521, L522 L42, L46, L48, L49, L50, L51, L53, L652 L601, L602, L56, L57, L58, L59, L62, L653
Cerebrovascular disease	430-437.x,438*	362.34, 460-436, 437-437.1, 437.9, 438, 781.4, 784.3, 997.0, 38.12(P),38.42(P)	I60, I61, I62, I63, I64, I65, I66, I67, G951, I68, I69, G45, G46, G936, G938‡	-	I60, I61, I62, I63, I64, I65, I66, I678, I672, I679, I676, I688, I69, G46, G45, G938, G951 H34, H357, G038, G039, G97‡	L291, L292, L293, L294, L295, L298, L299
Dementia	290.x*	290.x*, 331-331.2*	F00, F01, F03, F020A, F021A, G30, G310, G318, F051 A810	-	F00, F01, F020A, F021A, F03, G30, G310, G311, G318, F051, A810	-
Chronic pulmonary disease	490-496x*, 500-505*, 506.4*	415.0*, 416.8-416.9*, 491.x-494*, 496*	J209, J40, J980, J41, J42, J44, J43, J45, J46, J47, J60, J61, J62, J63, J64, J66, J67, J684 (all*)	-	I260, I278, I279, I249, J41, J42, J44, J980, J43, J45, J46, J47, I521	-
Rheumatological disease	710.0-710.1*, 710.4*, 714.0-714.2*, 714.81*, 725*	710.x, 714.x	M32, M34, M332, M05, M06, M138, M159, M199, M353 (all*)	-	M32, M33, M34, M06, M05, M09, M04, M120, M138, M159, M199, M351, M358, M359, M350, M013, M018, M360 (all *)	-

Peptic ulcer disease	531.4x-531.7x*, 532.4x-532.7x*, 533.4x-533.7x*,534.4x-534.7x*, 531.0x-531.3x, 532.0x-532.3x, 533.0x-533.3x,534.0x-534.3x,531.9, 532.9, 533.9, 534.9	531.xx-534.xx	K25, K26, K27, K28, K221	-	K25, K26, K27, K28, K221	-
Mild liver disease	571.2*, 571.4*, 571.5*, 571.6*	571.2*, 571.5-571.6*, 571.8-571.9*	K702, K703, K746, K73, K740, K742, K743, K761, K766, K745 (all *)	-	K702*, K70*3, K746*, K740, K742, K743, K761, K766, K745*, K721*, K760*, R162*, K741*, K769*	-
Diabetes (mild to moderate)	250.0x-250.3x*, 250.7x*	250.0x-2503.x*	E109, E119, E129, E139, E149, E101, E111, E121, E131, E141, E100, E110, E120, E130, E140, E141, E102, E112, E122, E132, E142, E105, E106, E107, E115, E116, E117, E125, E126, E127, E135, E136, E137, E146, E147, L921 (all *)	-	E109, E119, E129, E139, E149, E101, E111, E121, E131, E141, E100, E110, E120, E130, E140, E141, E102, E112, E122, E132, E142 (all *)	-
Diabetes with chronic complications	250.4x-250.6x*	250.4x-250.9x*	E103, E113, E123, E133, E143, E104, E106, E114, E116, E124, E126, E134, E136, E144, E146, E105, E115, E125, E135, E145 (all *)	-	E103, E113, E123, E133, E143, E104, E106, E114, E116, E124, E126, E134, E136, E144, E146, E105, E115, E125, E135, E145, E105, E106, E107, E115, E116, E117, E125, E126, E127, E135, E136, E137, E146, E147, L921, E108, E118, E128, E138, E148 (all *)†	-
Hemiplegia or paraplegia	342.x*. 344.1*	342.x, 344.x	G81, G820, G821, G822, G838 (all *)	-	G81, G82, G83, G958, N312, N318, N319, G122, G255, G938‡	-
Renal disease	582.x*, 583.0-583.7*, 585*, 586*, 588.x*	585-586*, V42.0*, V45.1*, V56.x*, 39.27(P)*, 39.42(P)*, 39.93-39.95(P)*, 54.98(P)*	N03, N084, N085, N019, N05, N07, N019, N171, N172, N18, N19, N25	-	N18, N19, Z940, Z992, Z49	L294, L295, L743, X41, X42, X401, X403, X408, X409
Any malignancy including lymphoma or leukaemia	140.x-172.x, 174.x-195.x, 200.xx-208.xx	140.x-171.x, 174.x-195.x*, 200.xx-208.x*, 273.0*, 273.3*, V10.46*, 60.5(P)*, 62.4-62.41(P)*	C00-C26, C30-C34, C37-C41, C43, C45, C461, C462, C463, C467, C47-C58, C60, C62-C63 **C61, C64-C67,** C68-C76, C798, C80-C85, C883, C887, C889, C90-C96¥	-	C00-C26, C30-C34, C37-C41, C45, C461, C462, C463, C467, C47-C58, C60, C62-C63 **C61, C64-C67,** C68-C76, C798, C80-C85, C883, C887, C889, C90-C96, D890, C880, Z85 (all*)¥	N05, N061‡

Moderate or severe liver disease	572.2-582.8*, 456.0-456.2x*	572.2-572.4*, 456.0-456.2x*, 39.1(P)*,42.91(P)*	K861, K862, K863, K868, K650, Z904, I85, I982	-	K861, K862, K863, I85, I982 (all *)†	L811, G10
Metastatic solid tumour	196.x-199.x	196.x-199.x*	C77, C78, C79, C80	-	C77, C78, C79, C80 (all*)†	-
AIDS	042.x-044.x	042.x-044.x	B20, B21, B22, B23, B24	-	B20, B21, B22, B23, B24	-

(P) follows all ICD-9-CM codes describing procedures rather than diagnoses

*Asterisked codes are used to define a comorbidity if present during either the index admission or previous admissions. Codes without an asterix are only used to define a comorbidity if present in admissions prior to the index admission.

†These codes take precedence over codes indicating the milder or less severe comorbidity within the Dartmouth-Manitoba adaptation only. E.g. In a patient who has diagnosis codes indicating the presence of diabetes with chronic complications, any codes indicating mild to moderate diabetes will be excluded from analysis. Similar rules also apply to moderate/severe liver disease and mild liver disease and also to metastatic solid cancer and any malignancy.

‡ The following code translations were judged not to make clinical sense or to be insufficiently precise and were therefore excluded from further analysis: L88 (pyoderma gangrenosum) within the peripheral vascular disease comorbidity; M219 (acquired deformity of limb) within the myocardial infarction comorbidity; R298 (other and unspecified symptoms and signs involving the nervous and musculoskeletal system), R291 (meningismus), R470 (dysphasia and aphasia), and T885 (other complications of anaesthesia) within the cerebrovascular comorbidity; G463 (brain stem stroke syndrome), G468 (other vascular syndromes of brain in cerebrovascular diseases), I630 (cerebral infarction due to thrombosis of precerebral arteries), I632 (cerebral infarction due to unspecified occlusion or stenosis of precerebral arteries), I650 (occlusion and stenosis of vertebral artery), I678 (other specified cerebrovascular diseases), and I679 (cerebrovascular disease, unspecified) within the Hemiplegia/paraplegia comorbidity. M611 (total excision of prostate and capsule of prostate) was excluded from the 'any malignancy' comorbidity for patients undergoing radical prostatectomy

¥Codes C61, C64-C67 represent codes used to define the presence of an index cancer. These codes were excluded from analysis for patients undergoing surgery for the respective cancer.

Appendix 3

HES EXTRACT SPECIFICATION FORM

(Please either type or write in black ink, as this form will be photocopied)

Data years (please tick): ☑

1989/90 ☐ 1990/91 ☐ 1991/92 ☐ 1992/93 ☐ 1993/94 ☐ 1994/95 ☐

1995/96 ✓ 1996/97 ✓ 1997/98 ✓ 1998/99 ✓ 1999/00 ✓ 2000/01 ✓

2001/02 ✓

Filter details *(See 2.3.1 to 2.4.2)* Epistat=3 OPER_1-4=M02 AND DIAG_1-7=(C64 or C65) OPER-1-4= M34 AND DIAG_1-7=C67 OPER_1-4=M61 AND DIAG_1-7=C61 OPER_1-4=M03 AND DIAG_1-7=(C64 or C65) To identify these and all subsequent episodes over a period of 2 years following the initial surgery and all episodes over a period of 2 years prior to admission for initial surgery. Individual patients will need to be identified using a unique anonymous patient identifier based on DOB, SEX and HOMEADD (as in our previous application ETT1359)

Fields to be extracted (please tick): ☑

Please note that the fields below are of the **General Table**, for **Augmented Care, Maternity and Psychiatric A** fields please refer to the Data Dictionary and write down the selected fields in Other Details on page 17.

Data Dictionary: http://tap.ccta.gov.uk/doh/hes_dd.nsf

ADMIDATE (Date of admission)	✓	DIAG_6 (Diagnosis)	✓	**HOMEADD** (Postcode of patient)	☐
ADMIMETH (Method of admission)	✓	DIAG_7 (Diagnosis)	✓	HOTEL(6) (Cost per day)	☐
ADMINCAT(5) (Admission category) group)	☐	DISDATE (Date of Discharge)	☐	HRGLATE(10) (Description of healthcare resource	☐

ADMISORC ☐ (Source of admission)	DISDEST ☐ (Destination of discharge)	HRGORIG[10] ☐ (Healthcare resorce group original value)
ADMISTAT[3] ☐ (Psychiatric patient status)	DISMETH ✓ (Method of discharge)	INTMANIG[4] ☐ (Intended management)
AIDSIND[4] ☐ (AIDS flag)	**DOB** ☐ (Date of Birth)	**LEGLCAT[5]** ☐ (Legal category)
BEDYEAR ☐ (Bed days within year)	ELECDATE ☐ (Date of decision to admit)	**LOPATID[4]** ☐ (Local patient identifier)
CARERSI[4] ☐ (Carer support indicator)	ELECDUR ✓ (Waiting time)	MAINSPEF ☐ (Main speciality)
CATEGORY ☐ (Administrative & legal status of patient)	ENDAGE ☐ (Age at the end of episode)	MARSTAT ☐ (Marital status)
CAUSE ☐ (External cause of injury or poisoning)	EPIDUR ✓ (Episode duration)	NEOCARE[3] ☐ (neonatal level of care)
CLASSPAT ☐ (Patient classification)	EPIEND ✓ (Date episode ended)	NEODUR ☐ (Baby's age in days)
~~**CONSULT[4]**~~ ~~☐~~ (Consultant code)	EPIKEY* ✓ (System record identifier)	**NEWNHSNO[4]** ☐ (NHS number)
CURRWARD +RESLADST ✓ episodes) (Current electrol ward) operation)	EPIORDER ✓ (Episode order) EPISTART ✓ (Date episode started)	NUMACP ✓ (No. of augmented care periods within OPER_1 ✓ (Contains information about patient's
DETNCAT[5] ☐ category) (Status of episode)	EPISTAT ☐ (Contains information about patient's operation)	OPER_2 ✓ (Detention
DHATREAT\HA ✓ (District of treatment) operation)	EPITYPE ☐ (Type of episode)	OPER_3 ✓ (Contains information about patient's
DHACOMP\HA ☐ (DHA comparison) operation)	ETHNOS[1] ✓ (Ethnic origin)	OPER_4 ✓ (Contains information about patient's
DIAG_1 ✓ (Diagnosis)	**GPPRAC[4]** ☐ (Code of GP practice)	OP_DTE_1 ✓ (Date of operation)
DIAG_2 ✓ (Diagnosis)	GPPRACHA[5] ☐ (Health Authority of GP practice)	OP_DTE_2 ✓ (Date of operation)
DIAG_3 ✓ (Diagnosis)	GPPRACRO[5] ☐ (Regional Office of GP practice)	OP_DTE_3 ✓ (Date of operation)
DIAG_4 ✓ (Diagnosis)	GROSS_A[11] ☐ (Clinical grossing)	OP_DTE_4 ✓ (Date of operation)
DIAG_5 ✓ (Diagnosis)	GROSS_B ☐ (Combined coverage & clinical grossing)	PCGCODE[5] ☐ (Primary care group code)

Fields to be extracted (please tick): ☑

Please note that the fields below are of the **General Table**, for **Augmented Care, Maternity and Psychiatric A** fields please refer to the Data Dictionary and write down the selected fields in Other Details (below).

Data Dictionary: http://tap.ccta.gov.uk/doh/hes_dd.nsf

PCGORIG[5] ☐
(Method of origination of PCG code)

PREOPDUR ✓
(Pre operation duration)

PROCODE[7] ✓
(provider code)

PRODMUT[7] ✓
(Hospital Provider)
of

POSOPDUR ✓
(Post operation duration)

PROVSPNO[4] ☐
(Hospital provider spell number)

PURCODE[9] ✓
(Purchaser code)

RECTYPE ☐
(Record type)

~~REFERRER[4] ☐~~
(Person referring patient – encrypted)

~~REGGMP[4] ☐~~
(Patient's GMP –encrypted)

RESCTY ☐
(County of residence)

RESDHA\HA ☐
(District HA of residence)

RESGOR ☐
(Government office region)

RESRHA\RO ☐
(RHA/RO of residence)

RESLADST ☐
(Local Authority District)

RHATREAT\RO ✓
(RHA/RO of treatment)

SAMPLED ☐
(Selected for sample)

SEX[8] ✓
(Sex of patient)

SITETRET ✓
(Site code of treatment)

SPELBGN ☐
(Beginning of spell)

SPELDUR ✓
(Duration of spell)

SPELEND ☐
(End of Spell)

STARTAGE ✓
(Age of admission)

SUBSPEF\TRET ☐
(Specialty of second consultant in a case shared care)

TOTCOST[6] ☐
(Total cost)

TREAT[6] ☐
(Cost of treatment)

VIND[2] ☐
(V code indicator)

WARD 81 ☐
(Patient's electoral ward in 1981)

WARD 91 ☐
(Patient's electoral ward in 1991)

WARDSTRT ✓
(Ward type at start of episode)

ALSO INTDAYS✓, DEPDAYS✓, ACPOUT✓ and HESID✓

(1) From 1995-96 onwards.
(2) Up to 1995-96, then replaced by ADMISTAT and NEOCARE.
(3) From 1996-97 onwards.
(4) From 1997-98 onwards.
(5) From 2000-01 onwards
(6) These fields are used for economic modelling, they provide relative rather than absolute costs.
(7) PRODMUT identifies an individual hospital provider by using the first 3 characters of PROCODE. Applicants will need to determine whether PRODMUT or PROCODE is essential to their purpose.
(8) The field SEX will be sensitive when combined with DOB and HOMEADD.
(9) Please refer to 3.1 in page 9.
(10) 1995-96 onwards
(11) Not available for 2000/01

☐ Fields in bold are sensitive and will need S&CAG approval.

Other details
CONSULT – data can be encrypted UNIQUE PATIENT ID (anonymous) based on HOMEADD, SEX and DOB

Appendix 4

Database Search strategies (Medline)

Urological Procedures Terms:

1 urol$.mp.
2 Urologic Surgical Procedures/
3 exp Prostatectomy/
4 prostatectomy.mp.
5 (prostat$ adj25 (excision$ or remov$)).mp.
6 (turp or turps).mp.
7 Nephrectomy/
8 nephrectomy.mp.
9 (kidney$ adj25 (excision$ or remov$)).mp.
10 Cystectomy/
11 cystectomy.mp.
12 (bladder$ adj25 (excision$ or remov$)).mp.
13 or/1-12

Surgeon or Hospital Volume Terms

14 ((physician$ or urol$ or surg$ or operat$ or hospital$) adj25 (volume$ or workload$ or caseload$ or performance)).mp.
15 exp Hospitals/
16 (volume$ or workload$ or caseload$ or performance).mp.
17 15 and 16
18 Workload/
19 or/14,17,18

Outcome Terms

20 "Outcome and Process Assessment (Health Care)"/
21 "Outcome Assessment (Health Care)"/
22 exp Treatment Outcome/
23 exp Medical Audit/
24 exp Mortality/
25 mortality.mp.
26 exp Morbidity/
27 morbidity.mp.
28 Length of Stay/
29 length of stay.mp.
30 ((duration or length or period) adj5 (stay or hospital$)).mp.
31 audit.mp.
32 or/21-31
33 exp Postoperative Complications/
34 complication$.mp.
35 or/21-33
36 or/21-34

Combined terms exluding animal only literature

37 Animal/ not (Animal/ and Human/)
38 (13 and 19 and 32) not 37 **(excludes complications)**
39 (13 and 19 and 35) not 37 **(includes postoperative complications)**
40 (13 and 19 and 36) not 37 **(includes complications)**

Appendix 5

Questions from the Surgeons' survey

1. How many years have you been a Consultant Urological Surgeon?

2. In an average year, how many of the following procedures do you perform, or are you as a consultant responsible for?

   Radical Prostatectomy
   Radical Cystectomy (ileal conduit)
   Radical Cystectomy (continent diversion)
   Radical Nephrectomy (open or laparoscopic, without vessel involvement)

3. In an average year, how many of the following procedures are performed in your hospital*? (including both NHS and private cases)
   (* where you perform most radical urological cancer surgery)

   Radical Prostatectomy
   Radical Cystectomy (ileal conduit)
   Radical Cystectomy (continent diversion)
   Radical Nephrectomy (open or laparoscopic, without vessel involvement)

4. Do you consider yourself to be part of a <u>local</u> urological multidisciplinary team?
   Yes/No
   If yes, how many Consultant Urologists are members of your team?

5. Do you consider yourself to be part of a <u>specialist</u> urological multidisciplinary team?
   Yes/No
   If yes, how many Consultant Urologists are members of your team?

6. In the preceding twelve months did you routinely refer patients to colleagues within your own hospital (equivalent to a local urological multidisciplinary team) for them to perform:

   Radical Prostatectomy
   Radical Cystectomy (ileal conduit)
   Radical Cystectomy (continent diversion)
   Radical Nephrectomy (open or laparoscopic, without vessel involvement)

   Yes/No

7. In the preceding twelve months did you routinely refer patients to colleagues within other hospitals (equivalent to a specialist urological multidisciplinary team) for them to perform:

   Radical Prostatectomy
   Radical Cystectomy (ileal conduit)
   Radical Cystectomy (continent diversion)
   Radical Nephrectomy (open or laparoscopic, without vessel involvement)

   Yes/No

8. Do you think that a minimum number of cases should be performed by a surgeon during a year for:

   Radical Prostatectomy
   Radical Cystectomy (ileal conduit)
   Radical Cystectomy (continent diversion)
   Radical Nephrectomy (open or laparoscopic, without vessel involvement)

   Yes/ No **If Yes, how many**?

9. Do you think that a LOCAL multidisciplinary team should be performing the following procedures?

   Radical Prostatectomy
   Radical Cystectomy (ileal conduit)
   Radical Cystectomy (continent diversion)
   Radical Nephrectomy (open or laparoscopic, without vessel involvement)

   Yes/ No **If Yes, how many?**

10. Do you think that a SPECIALIST multidisciplinary team should be performing the following procedures?

    Radical Prostatectomy
    Radical Cystectomy (ileal conduit)
    Radical Cystectomy (continent diversion)
    Radical Nephrectomy (open or laparoscopic, without vessel involvement)

    Yes/ No **If Yes, how many**?

11. In your expert opinion what beneficial effects might result from the implementation of the NICE Guidance?

12. In your expert opinion what harmful effects might result from the implementation of the NICE Guidance?

Thank you for completing this questionnaire

Please return it in the stamped addressed envelope provided

If you have any questions please do not hesitate to contact us